2023 PRIOR AUTHORIZATION CRITERIA

TABLE OF CONTENTS

Prior Authorization Group Description:
Actimmune PA
Drug Name(s)
Actimmune
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Acyclovir Topical PA
Drug Name(s)
Acyclovir
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Aimovig PA
Drug Name(s)
Aimovig
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 migraine headaches or more per month AND
4. ONE of the following:
    A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
    B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
    C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent AND
5. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:

Alosetron PA

Drug Name(s)

Alosetron Hydrochloride

Indications:

All FDA-Approved Indications.

Off-Label Uses:

Exclusion Criteria:

FDA labeled contraindication(s) 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:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Alpha-1-Proteinase Inhibitor PA - Prolastin-C
Drug Name(s)
Prolastin-C
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Anabolic Steroid PA – Danazol
Drug Name(s)
Danazol
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Anabolic Steroid PA – Oxandrolone
Drug Name(s)
Oxandrolone
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 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 female and is a child or adolescent with Turner syndrome AND is currently receiving growth hormone OR
    C. Patient has weight loss following extensive surgery, chronic infections, or severe trauma OR
    D. Patient has chronic pain from osteoporosis OR
    E. Patient is on long-term administration of oral or injectable corticosteroids 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Androgen Injectable PA - testosterone cypionate
Drug Name(s)
Testosterone Cypionate
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 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 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:
Prescriber Restrictions:
Coverage Duration:

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

Prior Authorization Group Description:
Androgen Injectable PA - testosterone enanthate
Drug Name(s)
Testosterone Enanthate
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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
1. 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 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 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be 6 months for delayed puberty, 12 months for all other indications

Other Criteria:

Prior Authorization Group Description:
Androgen Oral PA
Drug Name(s)
Methyltestosterone
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 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 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be 6 months for delayed puberty, 12 months for all other indications
Other Criteria:

Prior Authorization Group Description:
Androgen Topical PA
Drug Name(s)
Androderm
Testosterone
Testosterone Pump
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 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 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:

Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Antipsychotics PA
Drug Name(s)
Aripiprazole
Aripiprazole Odt
Asenapine Maleate Sl
Chlorpromazine Hydrochloride
Clozapine
Clozapine Odt
Fanapt
Fanapt Titration Pack
Fluphenazine Decanoate
Fluphenazine Hydrochloride
Haloperidol
Haloperidol Decanoate
Haloperidol Lactate
Loxapine
Lybalvi
Molindone Hydrochloride
Olanzapine
Olanzapine Odt
Paliperidone Er
Perphenazine
Quetiapine Fumarate
Quetiapine Fumarate Er
Rexulti
Risperidone
Risperidone Odt
Secuado
Thioridazine Hcl
Thiothixene
Trifluoperazine Hcl
Versacloz
Ziprasidone Mesylate
Zyprexa Relprevv
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Apomorphine Inj PA
Drug Name(s)
Apokyn
Apomorphine Hydrochloride
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Arcalyst PA
Drug Name(s)
Arcalyst
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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) AND
    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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Armodafinil PA
Drug Name(s)
Armodafinil
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require BOTH of 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 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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Atopic Dermatitis PA – Pimecrolimus
Drug Name(s)
Pimecrolimus
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Atopic Dermatitis PA – Tacrolimus
Drug Name(s)
Tacrolimus
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Atovaquone PA
Drug Name(s)
Atovaquone
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:

Auryxia PA

Drug Name(s)

Auryxia

Indications:

All FDA-Approved Indications.

Off-Label Uses:

Exclusion Criteria:

Requested agent will be used as iron replacement therapy to treat iron deficiency anemia AND FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of hyperphosphatemia AND BOTH of the following:
    A. Patient has chronic kidney disease AND
    B. Patient is on dialysis

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Belsomra PA
Drug Name(s)
Belsomra
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benlysta IV PA
Drug Name(s)
Benlysta IV
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
For diagnosis of active systemic lupus erythematosus (SLE) disease, patient is 5 years of age or over. For diagnosis of active lupus nephritis (LN), patient is 5 years of age or over.
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Benlysta SC PA
Drug Name(s)
Benlysta SC
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
        a. 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:
For diagnosis of active systemic lupus erythematosus (SLE) disease, patient is 18 years of age or over.
For diagnosis of active lupus nephritis (LN), patient is 18 years of age or over.

Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Clobazam
Drug Name(s)
Clobazam
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Clorazepate
Drug Name(s)
Clorazepate Dipotassium
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Diazepam
Drug Name(s)
Diazepam
Diazepam Intensol
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Lorazepam
Drug Name(s)
Lorazepam
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Oxazepam
Drug Name(s)
Oxazepam
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Benzodiazepines PA – Sympazan
Drug Name(s)
Sympazan
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Biologic Immunomodulators PA – Cosentyx
Drug Name(s)
Cosentyx
Cosentyx Sensoready Pen
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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

Age Restriction:
Prescriber Restrictions:
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, or non-radiographic axial spondyloarthritis

Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group Description:
Biologic Immunomodulators PA – Enbrel
Drug Name(s)
Enbrel
Enbrel Mini
Enbrel Sureclick
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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

Age Restriction:
Prescriber Restrictions:
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, or juvenile idiopathic arthritis

NO prerequisites are required for a diagnosis of ankylosing spondylitis

Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

Formulary conventional topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group Description:
Biologic Immunomodulators PA – Humira
Drug Name(s)
Humira
Humira Pediatric Crohns Disease Starter Pack
Humira Pen
Humira Pen-Cd/Uc/Hs Starter
Humira Pen-Pediatric Uc Starter Pack
Humira Pen-Ps/Uv Starter
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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

Age Restriction:
Prescriber Restrictions:
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 topical or systemic antipsoriatic agents 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

Prior Authorization Group Description:
Biologic Immunomodulators PA – Rinvoq
Drug Name(s)
Rinvoq
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
            1. 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
            2. 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
            3. 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
Age Restriction:

Prescriber Restrictions:
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

Use of ONE preferred TNF (Enbrel or Humira) is required for diagnoses of ankylosing spondylitis, rheumatoid arthritis, or psoriatic arthritis

Only the preferred TNF Humira is required for diagnoses of ulcerative colitis or Crohn's disease

Use of TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) are required for diagnosis of moderate to severe atopic dermatitis

NO preferred TNF agents are required for diagnosis of non-radiographic Axial Spondyloarthritis

Prior Authorization Group Description:
Biologic Immunomodulators PA – Skyrizi
Drug Name(s)
Skyrizi
Skyrizi Pen
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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
Age Restriction:
Prescriber Restrictions:
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 topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Formulary conventional agents for psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

Prior Authorization Group Description:
Biologic Immunomodulators PA – Stelara
Drug Name(s)
Stelara
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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

Age Restriction:
Prescriber Restrictions:
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 topical or systemic antipsoriatic agents 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

Prior Authorization Group Description:
Biologic Immunomodulators PA – Tremfya
Drug Name(s)
Tremfya
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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

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

Age Restriction:
Prescriber Restrictions:
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 topical or systemic antipsoriatic agents include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

Prior Authorization Group Description:
Biologic Immunomodulators PA - Xeljanz Solution
Drug Name(s)
Xeljanz Solution
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:
Use of ONE preferred TNF (Enbrel or Humira) is required for diagnosis of juvenile idiopathic arthritis

Prior Authorization Group Description:
Biologic Immunomodulators PA - Xeljanz Tablet
Drug Name(s)
Xeljanz Tablet
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:
Use of ONE preferred TNF (Enbrel or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, or ankylosing spondylitis

Only the preferred TNF Humira is required for diagnosis of ulcerative colitis

Prior Authorization Group Description:
Biologic Immunomodulators PA - Xeljanz XR
Drug Name(s)
Xeljanz Xr
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:
Use of ONE preferred TNF (Enbrel or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, or ankylosing spondylitis

Only the preferred TNF Humira is required for diagnosis of ulcerative colitis

Prior Authorization Group Description:
Bivigam/Flebogamma/Gammaplex/Octagam/Privigen PA
Drug Name(s)
Gammaplex
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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., Humira), 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:
Prescriber Restrictions:
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, Gilenya, glatiramer, Glatopa, Mayzent, Plegridy, Rebif, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:
    i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, 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.

Prior Authorization Group Description:
Budesonide Oral ER PA – Entocort
Drug Name(s)
Budesonide
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Budesonide Oral ER PA – Uceris
Drug Name(s)
Budesonide Er
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:

Carglumic PA

Drug Name(s)

Carglumic Acid

Indications:

All FDA-Approved Indications, Some Medically-Accepted Indications.

Off-Label Uses:

Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

Exclusion Criteria:

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:

Prescriber Restrictions:

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:

Prior Authorization Group Description:
Chenodal PA
Drug Name(s)
Chenodal
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Cinacalcet PA
Drug Name(s)
Cinacalcet Hydrochloride
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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. An FDA approved indication or an indication that is 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] 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. A diagnosis of hypercalcemia due to parathyroid carcinoma OR
    C. 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
    D. Another indication that is supported in CMS approved compendia for the requested agent not otherwise excluded from Part D

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Fulphila
Drug Name(s)
Fulphila
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Granix
Drug Name(s)
Granix
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Leukine
Drug Name(s)
Leukine
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Nivestym
Drug Name(s)
Nivestym
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Udenyca
Drug Name(s)
Udenyca
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Colony Stimulating Factors PA – Ziextenzo
Drug Name(s)
Ziextenzo
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Corlanor PA
Drug Name(s)
Corlanor
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
            1. Patient is on a maximally tolerated dose of beta blocker (e.g., bisoprolol, carvedilol, metoprolol) OR
            2. Patient has an intolerance, FDA labeled contraindications, or hypersensitivity to a beta blocker

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Cresemba PA
Drug Name(s)
Cresemba
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 6 months
Other Criteria:

Prior Authorization Group Description:
Cystadrops PA
Drug Name(s)
Cystadrops
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Cystaran PA
Drug Name(s)
Cystaran
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. Patient has an FDA labeled indication for the requested agent

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Cystinosis Agents PA – Cystagon
Drug Name(s)
Cystagon
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Dalfampridine PA
Drug Name(s)
Dalfampridine Er
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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. If indicated, the requested agent will be used in combination with a disease modifying agent [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, Gilenya, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia] 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. If indicated, the requested agent will be used in combination with a disease modifying agent [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, Gilenya, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Vumerity, Zeposia] 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Dayvigo PA
Drug Name(s)
Dayvigo
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Droxidopa PA
Drug Name(s)
Droxidopa
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Dupixent PA
Drug Name(s)
Dupixent
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require BOTH of:
1. ONE of:
    A. Patient (pt) has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of:
        i. ONE of:
            a. Pt has tried and failed a topical steroid (e.g., triamcinolone) AND for pts 2 years of age or over, a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR
            b. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical steroid AND for pts 2 years of age or over, a topical calcineurin inhibitor AND
        ii. Pt will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR
    B. Pt has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND ALL of:
        i. Pt has ONE of:
            a. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months OR
            b. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR
            c. Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered OR
            d. Pt has a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted AND
        ii. ONE of:
            a. Pt is NOT currently being treated with the requested agent AND is currently being treated with a maximally tolerated inhaled corticosteroid (ICS) OR
            b. Pt is currently being treated with the requested agent AND ONE of:
                1. Pt is currently being treated with an ICS that is adequately dosed to control symptoms OR
                2. Pt is currently being treated with a maximally tolerated ICS OR
                3. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to an ICS AND
        iii. ONE of:

a. Pt is currently being treated with ONE of:
1. A long-acting beta-2 agonist (LABA) OR

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 chronic rhinosinusitis with nasal polyposis (CRSwNP), patient is 18 years of age or over. For diagnosis of eosinophilic esophagitis (EoE), patient is 12 years of age or over. For diagnosis of PN, patient is 18 years of age or over.

Prescriber Restrictions:

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:

2. A leukotriene receptor antagonist (LRTA) OR
3. A long-acting muscarinic antagonist (LAMA) OR
4. Theophylline OR

b. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to a LABA, LRTA, LAMA, or theophylline AND

iv. Pt will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND

v. Pt 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. Pt has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following:

i. BOTH of:

a. ONE of:

1. Pt has tried and had an inadequate response to an oral systemic corticosteroid AND an intranasal corticosteroid (e.g., fluticasone) OR
2. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to an oral systemic corticosteroid AND an intranasal corticosteroid AND

b. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR

D. Pt has a diagnosis of eosinophilic esophagitis (EoE) confirmed by esophageal biopsy OR

E. Pt 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:

1. Pt has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. ONE of:
    A. BOTH of:
        i. Pt has a diagnosis of moderate-to-severe atopic dermatitis AND
        ii. Pt will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR
    B. Pt has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND ALL of:
        i. ONE of:
            a. Pt is currently being treated with standard therapy [e.g., ICS, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline] OR
            b. Pt has an intolerance, hypersensitivity, or FDA labeled contraindication to a standard therapy
            AND
        ii. Pt will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
        iii. Pt 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. Pt has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND the following:
        i. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR
    D. Pt has a diagnosis of eosinophilic esophagitis (EoE) OR
    E. Pt has a diagnosis of prurigo nodularis (PN) AND
3. Pt has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:
Emgality PA
Drug Name(s)
Emgality
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require BOTH of 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 migraine headaches or more per month AND
        iii. ONE of the following:
            a. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
            b. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
            c. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent 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 AND
2. 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. ONE of the following:
    A. BOTH of the following:
        i. Patient has a diagnosis of migraine AND
        ii. The requested agent is being used for migraine prophylaxis OR
    B. Patient has a diagnosis of episodic cluster headache 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 calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Emsam PA

Drug Name(s)

Emsam

Indications:

All Medically-Accepted Indications.

Off-Label Uses:

Exclusion Criteria:

Required Medical Information:

Criteria for initial approval require ALL 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:

Prescriber Restrictions:

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

Prior Authorization Group Description:

Epclusa PA

Drug Name(s)

Epclusa

Sofosbuvir/Velpatasvir

Indications:

All Medically-Accepted Indications.

Off-Label Uses:

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 dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. ONE of the following:
    A. The requested agent is the preferred agent: Epclusa OR
    B. The requested agent is the non-preferred agent: sofosbuvir/velpatasvir AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
        iv. 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 TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:

Prescriber Restrictions:

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:

Prior Authorization Group Description:
Epidiolex PA
Drug Name(s)
Epidiolex
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Erythropoietin Stimulating Agents PA – Aranesp
Drug Name(s)
Aranesp Albumin Free
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 (treatment period extends to 8 weeks post 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:
Prescriber Restrictions:
Coverage Duration:
6 months for chemotherapy, 12 months for other indications
Other Criteria:

Prior Authorization Group Description:
Erythropoietin Stimulating Agents PA - Epogen/Procrit
Drug Name(s)
Procrit
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 13 g/dL or less 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 (treatment period extends to 8 weeks post 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:
Prescriber Restrictions:
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.

Prior Authorization Group Description:
Erythropoietin Stimulating Agents PA – Retacrit
Drug Name(s)
Retacrit
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 13 g/dL or less 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 (treatment period extends to 8 weeks post 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:
Prescriber Restrictions:

Coverage Duration:
1 month for surgery (reduce transfusion possibility), 6 months for chemo, 12 months for other
Other Criteria:

Prior Authorization Group Description:
Esbriet PA
Drug Name(s)
Pirfenidone
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:

Eysuvis PA

Drug Name(s)

Eysuvis

Indications:

All FDA-Approved Indications.

Off-Label Uses:

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:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 1 month

Other Criteria:

Prior Authorization Group Description:
Fasenra PA
Drug Name(s)
Fasenra
Fasenra Pen
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 has ONE of the following:
    A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months OR
    B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR
    C. Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered OR
    D. Patient has a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted AND
3. ONE of the following:
    A. Patient is NOT currently being treated with the requested agent AND is currently being treated with a maximally tolerated inhaled corticosteroid (ICS) OR
    B. Patient is currently being treated with the requested agent AND ONE of the following:
        i. Patient is currently being treated with an inhaled corticosteroid that is adequately dosed to control symptoms OR
        ii. Patient is currently being treated with a maximally tolerated inhaled corticosteroid OR
        iii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an inhaled corticosteroid AND
4. ONE of the following:
    A. Patient is currently being treated with ONE of the following:
        i. A long-acting beta-2 agonist (LABA) OR
        ii. A leukotriene receptor antagonist (LRTA) OR
        iii. A long-acting muscarinic antagonist (LAMA) OR
        iv. Theophylline OR
    B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a LABA, LRTA, LAMA, or theophylline AND

Initial criteria continues: see Other Criteria
Age Restriction:
Patient is 12 years of age or over
Prescriber Restrictions:

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:

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. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
7. 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. ONE of the following:
    A. Patient is currently being treated with standard therapy [e.g., ICS, LABA, LRTA, LAMA, theophylline] OR
    B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy 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. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
7. The requested dose is within the FDA labeled dosing for the requested indication

Prior Authorization Group Description:
Fentanyl Oral PA - Fentanyl lozenge
Drug Name(s)
Fentanyl Citrate Oral Transmucosal
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 the following:
        i. There is evidence of a claim that the patient is currently taking a long-acting opioid with the oral fentanyl 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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Fintepla PA
Drug Name(s)
Fintepla
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Focalin PA
Drug Name(s)
Dexmethylphenidate Hydrochloride
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Gammagard/Gammaked/Gamunex-C PA
Drug Name(s)
Gammagard Liquid
Gammagard S/D Iga Less Than 1Mcg/Ml
Gamunex-C
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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., Humira), 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:

Prescriber Restrictions:

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, Gilenya, glatiramer, Glatopa, Mayzent, Plegridy, Rebif, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:
    i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, 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.

Prior Authorization Group Description:
Gattex PA
Drug Name(s)
Gattex
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Growth Hormone PA – Omnitrope
Drug Name(s)
Omnitrope
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
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)

Prior Authorization Group Description:
HAE PA – Cinryze
Drug Name(s)
Cinryze
Indications:
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 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-nl-C1INH (Type III)]: Normal levels of C4 and C1-INH (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, or kininogen1 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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
HAE PA – Haegarda
Drug Name(s)
Haegarda
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 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 (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, or kininogen1 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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
HAE PA – Icatibant
Drug Name(s)
Icatibant Acetate
Sajazir
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 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 (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, or kininogen1 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

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

Age Restriction:
Prescriber Restrictions:
Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Harvoni PA
Drug Name(s)
Harvoni
Ledipasvir/Sofosbuvir
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA dosing for the requested indication AND
5. ONE of the following:
    A. The requested agent is the preferred agent: Harvoni OR
    B. The requested agent is the non-preferred agent: ledipasvir/sofosbuvir AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
        iv. 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 TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Hetlioz Capsule PA
Drug Name(s)
Tasimelteon
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. 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 Restrictions:
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:

Prior Authorization Group Description:
High Risk Medication PA - All Starts
Drug Name(s)
Benztropine Mesylate
Clemastine Fumarate
Cyproheptadine Hydrochloride
Dicyclomine Hydrochloride
Diphenoxylate Hydrochloride/Atropine Sulfate
Hydroxyzine Hydrochloride
Promethazine Hydrochloride
Promethegan
Scopolamine
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 documented that s/he discussed risks and potential side effects of the requested high-risk medication with the patient

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Imiquimod PA
Drug Name(s)
Imiquimod
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. 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:
Prescriber Restrictions:
Coverage Duration:
4 months for Actinic keratosis, other diagnoses - see Other Criteria
Other Criteria:
2 months for Superficial basal cell carcinoma, Squamous cell carcinoma, and Basal cell carcinoma

4 months for External genital and/or perianal warts/condyloma acuminata

12 months for All other diagnoses

Prior Authorization Group Description:
Inbrija PA
Drug Name(s)
Inbrija
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require ALL of the following:

1. The requested agent will be used for intermittent treatment of OFF episodes in patients with Parkinson's disease AND
2. Patient is receiving concurrent therapy with carbidopa/levodopa AND
3. Patient will NOT be using a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine) in combination with, or within 2 weeks of, the requested agent

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Injectable Oncology PA
Drug Name(s)
Folotyn
Fulvestrant
Lumoxiti
Margenza
Nelarabine
Ontruzant
Synribo
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR
            b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
            c. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Iron Chelating Agents PA – Exjade
Drug Name(s)
Deferasirox (Exjade)
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Iron Chelating Agents PA – Jadenu
Drug Name(s)
Deferasirox (Jadenu)
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Ivermectin Cream PA
Drug Name(s)
Ivermectin Cream
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Ivermectin Tablet PA
Drug Name(s)
Ivermectin Tablet
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 4 months
Other Criteria:

Prior Authorization Group Description:
Kalydeco PA
Drug Name(s)
Kalydeco
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:
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:

Prior Authorization Group Description:
Kerendia PA
Drug Name(s)
Kerendia
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:

Korlym PA

Drug Name(s)

Korlym

Indications:

All FDA-Approved Indications.

Off-Label Uses:

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 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 has failed surgical resection OR
    B. Patient is NOT a candidate for surgical resection

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Leuprolide PA
Drug Name(s)
Eligard
Leuprolide Acetate
Lupron Depot (1-Month)
Lupron Depot (3-Month)
Lupron Depot (4-Month)
Lupron Depot (6-Month)
Lupron Depot-Ped (1-Month)
Lupron Depot-Ped (3-Month)
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Lidocaine Topical PA - Lidocaine Ointment
Drug Name(s)
Lidocaine Ointment
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Lidocaine Topical PA - Lidocaine Patch
Drug Name(s)
Lidocaine Patch
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Lidocaine Topical PA - Lidocaine Solution
Drug Name(s)
Lidocaine Solution
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Lidocaine Topical PA - Lidocaine/prilocaine Cream
Drug Name(s)
Lidocaine/Prilocaine
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Lidocaine Topical PA – ZTlido
Drug Name(s)
Ztlido
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Linezolid PA
Drug Name(s)
Linezolid
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for approval require ALL of the following:

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 AND the patient has an FDA labeled indication for the requested agent 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:
Prescriber Restrictions:
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

3. Patient will NOT be using the requested agent in combination with Sivextro (tedizolid) for the same infection AND
4. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:
Memantine ER PA
Drug Name(s)
Memantine Hydrochloride Er
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
PA does NOT apply to patients greater than or equal to 30 years of age
Criteria for approval require the following:

2. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Memantine PA
Drug Name(s)
Memantine Hcl Titration Pak
Memantine Hydrochloride
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
PA does NOT apply to patients greater than or equal to 30 years of age
Criteria for approval require the following:

2. 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Methylin PA
Drug Name(s)
Methylphenidate Hydrochloride (Methylin)
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for approval require the following:

2. Patient has an FDA labeled indication for the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Methylphenidate ER Tablet PA
Drug Name(s)
Methylphenidate Hydrochloride Er Tablet
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for approval require the following:

2. Patient has an FDA labeled indication for the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Migranal PA
Drug Name(s)
Dihydroergotamine Mesylate (Migranal)
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 acute triptan agents with differing active ingredients (e.g., sumatriptan, rizatriptan) OR
    B. Patient has an intolerance or hypersensitivity to TWO acute triptan agents with differing active ingredients OR
    C. Patient has an FDA labeled contraindication to TWO acute 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Modafinil PA
Drug Name(s)
Modafinil
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require BOTH of the following:

2. 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 AND
3. 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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Avonex
Drug Name(s)
Avonex
Avonex Pen
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Betaseron
Drug Name(s)
Betaseron
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA - Dimethyl Fumarate
Drug Name(s)
Dimethyl Fumarate
Dimethyl Fumarate Starterpack
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Gilenya
Drug Name(s)
Fingolimod
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Glatiramer
Drug Name(s)
Copaxone
Glatiramer Acetate
Glatopa
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Mayzent
Drug Name(s)
Mayzent
Mayzent Starter Pack
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Plegridy
Drug Name(s)
Plegridy
Plegridy Starter Pack
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Rebif
Drug Name(s)
Rebif
Rebif Rebidose
Rebif Rebidose Titration Pack
Rebif Titration Pack
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
MS PA – Vumerity
Drug Name(s)
Vumerity
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Myalept PA
Drug Name(s)
Myalept
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 (30µU/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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Natpara PA
Drug Name(s)
Natpara
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Increased baseline risk for osteosarcoma (e.g., Paget's disease of bone, unexplained elevations of alkaline phosphatase, hereditary disorders predisposing to osteosarcoma, history of external beam or implant radiation therapy involving the skeleton, pediatric and young adult patients with open epiphyses)
Required Medical Information:
Criteria for initial approval require ALL of the following:
1. Patient has a diagnosis of hypocalcemia associated with hypoparathyroidism AND
2. Patient does NOT have a baseline vitamin D level below the testing laboratory's lower limit of normal AND
3. Patient's baseline serum calcium level (albumin-corrected) is above 7.5 mg/dL AND
4. Patient will NOT be using the requested agent in combination with alendronate 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 hypocalcemia associated with hypoparathyroidism AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with alendronate for the requested indication
Age Restriction:
Prescriber Restrictions:
Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, nephrologist) 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:

Prior Authorization Group Description:
Nuedexta PA
Drug Name(s)
Nuedexta
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 pseudobulbar affect OR
    B. Patient has 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 a monoamine oxidase inhibitor (MAOI) [e.g., Marplan (isocarboxazid), Nardil (phenelzine), and Parnate (tranylcypromine)]

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Nuplazid PA
Drug Name(s)
Nuplazid
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

2. Patient has an FDA labeled indication for the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Nurtec PA
Drug Name(s)
Nurtec
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 episodic migraine prophylaxis AND ALL of the following:
        i. Patient has 4 migraine headaches or more per month AND
        ii. ONE of the following:
            a. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
            b. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agent OR
            c. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent AND
        iii. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 Months
Other Criteria:
Criteria for renewal 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 episodic 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

Prior Authorization Group Description:
Ocaliva PA
Drug Name(s)
Ocaliva
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
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)

Prior Authorization Group Description:
Ofev PA
Drug Name(s)
Ofev
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require the following:

2. 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Oncology Immunotherapy PA – Opdivo
Drug Name(s)
Opdivo
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR
            b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR
            c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND
        iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Opioids ER PA - Fentanyl Patch
Drug Name(s)
Fentanyl
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. ALL of the following:
            a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy 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 confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND
            f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Opioids ER PA – Hydrocodone
Drug Name(s)
Hydrocodone Bitartrate Er
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. ALL of the following:
            a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy 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 confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND
            f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Opioids ER PA – Morphine
Drug Name(s)
Morphine Sulfate Er
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. ALL of the following:
            a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy 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 confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND
            f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Opioids ER PA – Tramadol
Drug Name(s)
Tramadol Hcl Er
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require the following:

1. ONE of the following:
    A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR
    B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:
        i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
        ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
        iii. ALL of the following:
            a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:
                1. Diagnosis AND
                2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy 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 confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND
            f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Orkambi PA
Drug Name(s)
Orkambi
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:
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:

Prior Authorization Group Description:
Palynziq PA
Drug Name(s)
Palynziq
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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 approval will be for 9 months, renewal approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Panretin PA
Drug Name(s)
Panretin
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Pegylated Interferon PA
Drug Name(s)
Pegasys
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for approval require the following:

2. 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 or AASLD/IDSA guidelines 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:
Prescriber Restrictions:
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 or AASLD/IDSA guideline supported

Prior Authorization Group Description:
Posaconazole PA
Drug Name(s)
Noxafil
Posaconazole Dr
Posaconazole Susp
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for initial approval require the following:

2. 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:
Prescriber Restrictions:
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

Prior Authorization Group Description:

Prolia PA

Drug Name(s)

Prolia

Indications:

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:
Prescriber Restrictions:
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 limits of the testing laboratory's normal range OR
B. Pt 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
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

Prior Authorization Group Description:

Promacta PA

Drug Name(s)

Promacta

Indications:

All Medically-Accepted Indications.

Off-Label Uses:

Exclusion Criteria:

Required Medical Information:

Criteria for initial approval require ONE of the following:

1. Patient has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
    - A. Patient has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
    - B. Patient has an intolerance or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
    - C. Patient has an FDA labeled contraindication to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
    - D. Patient has had an insufficient response to a splenectomy OR
2. Patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:
    - A. Patient's platelet count is less than 75 x 10^9/L AND the intent is to increase platelet counts sufficiently to initiate pegylated interferon therapy OR
    - B. Patient is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia OR
3. Patient has a diagnosis of severe aplastic anemia (SAA) AND ALL of the following:
    - A. Patient has at least 2 of the following blood criteria:
        - i. Neutrophils less than 0.5 X 10^9/L OR
        - ii. Platelets less than 20 X 10^9/L OR
        - iii. Reticulocytes less than 1% corrected [percentage of actual hematocrit (Hct) to normal Hct] or reticulocyte count less than 60 X 10^9/L AND
    - B. Patient has at least 1 of the following marrow criteria:
        - i. Severe hypocellularity is less than 25% OR
        - ii. Moderate hypocellularity is 25-50% with hematopoietic cells representing less than 30% of residual cells AND
    - C. ONE of the following:
        - i. BOTH of the following:
            1. Patient will be using the requested agent as first-line treatment AND
            2. Patient will use the requested agent in combination with standard immunosuppressive therapy [i.e., antithymocyte globulin (ATG) AND cyclosporine] OR

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

ii. Patient has tried and had an insufficient response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy OR

4. 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 persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:

i. Patient's platelet count is 50 x 10^9/L or greater OR

ii. Patient's platelet count has increased sufficiently to avoid clinically significant bleeding OR

B. Patient has a diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following:

i. ONE of the following:

1. Patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin OR

2. Patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin at the same time as the requested agent AND

ii. ONE of the following:

1. Patient's platelet count is 90 x 10^9/L or greater OR

2. Patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C OR

C. Patient has a diagnosis of severe aplastic anemia (SAA) AND ONE of the following:

i. BOTH of the following:

1. Patient is using the requested agent in combination with standard immunosuppressive therapy [i.e., antithymocyte globulin (ATG) AND cyclosporine] for the first-line treatment of severe aplastic anemia AND

2. Patient has had a response by 6 months defined as meeting TWO of the following values:

a. An absolute neutrophil count (ANC) greater than 500/mcL OR

b. Platelet count greater than 20 x 10^9/L OR

c. Reticulocyte count greater than 60,000/mcL OR

ii. Patient is not using the requested agent in combination with standard immunosuppressive therapy AND has had a hematological response by week 16 OR

D. Patient has another indication that is supported in CMS approved compendia and has had clinical benefit with the requested agent

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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Adempas
Drug Name(s)
Adempas
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
FDA labeled contraindications to the requested agent
Required Medical Information:
Criteria for initial approval require the following:

2. 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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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:

Prescriber Restrictions:

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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Ambrisentan
Drug Name(s)
Ambrisentan
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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 request is for ambrisentan for use in combination with Adcirca or Alyq (tadalafil) 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 ambrisentan with Adcirca or Alyq (tadalafil)], 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:
Prescriber Restrictions:

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

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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Bosentan
Drug Name(s)
Bosentan
Tracleer
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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 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

Initial criteria continues: see Other Criteria
Age Restriction:

Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

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 PAH pharmacotherapy AND
    3. All three agents in the triple therapy are from a different therapeutic class 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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Opsumit
Drug Name(s)
Opsumit
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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. 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

Age Restriction:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Sildenafil
Drug Name(s)
Sildenafil Citrate
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Concurrently taking another phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] 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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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 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

Initial criteria continues: see Other Criteria
Age Restriction:
Prescriber Restrictions:

Coverage Duration:
Approval will be for 12 months
Other Criteria:

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 PAH pharmacotherapy AND
    3. All three agents in the triple therapy are from a different therapeutic class 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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Tadalafil
Drug Name(s)
Alyq
Tadalafil
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Concurrently taking another phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] 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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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 request is for Adcirca or Alyq (tadalafil) for use in combination with Letairis (ambrisentan) 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 Adcirca or Alyq (tadalafil) with Letairis (ambrisentan)], 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:
Prescriber Restrictions:
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

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

Prior Authorization Group Description:
Pulmonary Hypertension PA – Uptravi
Drug Name(s)
Uptravi
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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 BOTH of the following:
                1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
                2. 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

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:
Pulmonary Hypertension PA – Ventavis
Drug Name(s)
Ventavis
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 AND provided clinical justification to support that the patient is at risk if therapy is changed 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

Age Restriction:
Prescriber Restrictions:
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.

Prior Authorization Group Description:
Pyrimethamine PA
Drug Name(s)
Pyrimethamine
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 6 months
Other Criteria:

Prior Authorization Group Description:
Quinine PA
Drug Name(s)
Quinine Sulfate
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
7 days for malaria, 10 days for babesiosis, 12 months for all other diagnoses
Other Criteria:

Prior Authorization Group Description:
Regranex PA
Drug Name(s)
Regranex
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Repatha PA
Drug Name(s)
Repatha
Repatha Pushtronex System
Repatha Sureclick
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) OR
        iii. Patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, 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 100 mg/dL or greater 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 two mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene OR
        ii. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C 300 mg/dL or greater (7.76 mmol/L or greater) OR
        iii. Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) OR
    C. A diagnosis of established cardiovascular disease [angina pectoris, coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease (CeVD) or peripheral vascular disease (PVD) or after coronary revascularization or carotid endarterectomy] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke, and coronary revascularization OR

D. A diagnosis of primary hyperlipidemia (not associated with HeFH, HoFH, or established cardiovascular disease) OR

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

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:

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 (*intolerance is defined as inability to tolerate the lowest FDA approved starting dose of a statin) 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

Prior Authorization Group Description:
Rho Kinase Inhibitor PA – Rhopressa
Drug Name(s)
Rhopressa
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of open-angle glaucoma or ocular hypertension AND
2. ONE of the following:
    a. Patient has tried and failed at least ONE generic ophthalmic prostaglandin (e.g., latanoprost) OR
    b. Patient has an intolerance or hypersensitivity to ONE generic ophthalmic prostaglandin (e.g., latanoprost) OR
    c. Patient has an FDA labeled contraindication to ONE generic ophthalmic prostaglandin (e.g., latanoprost)

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 open-angle glaucoma or ocular hypertension AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Rho Kinase Inhibitor PA – Rocklatan
Drug Name(s)
Rocklatan
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of open-angle glaucoma or ocular hypertension AND
2. ONE of the following:
    a. Patient has tried and failed at least ONE generic ophthalmic prostaglandin (e.g., latanoprost) OR
    b. Patient has an intolerance or hypersensitivity to ONE generic ophthalmic prostaglandin (e.g., latanoprost) OR
    c. Patient has an FDA labeled contraindication to ONE generic ophthalmic prostaglandin (e.g., latanoprost)

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 open-angle glaucoma or ocular hypertension AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Ritalin PA
Drug Name(s)
Methylphenidate Hydrochloride (Ritalin)
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Roflumilast PA
Drug Name(s)
Roflumilast
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:

Samsca PA

Drug Name(s)

Tolvaptan

Indications:

All FDA-Approved Indications.

Off-Label Uses:

Exclusion Criteria:

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

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 (Initial dose is 15 mg once daily, may be increased to 30 mg once daily after 24 hours, up to a maximum daily dose of 60 mg, as needed to achieve the desired level of serum sodium. Do not administer the requested agent for more than 30 days to minimize the risk of liver injury)

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 30 days

Other Criteria:

Prior Authorization Group Description:
Sapropterin PA
Drug Name(s)
Javygtor
Sapropterin Dihydrochloride
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Self - Administered Oncology PA
Drug Name(s)
Abiraterone Acetate
Alecensa
Alunbrig
Ayvakit
Balversa
Besremi
Bexarotene Cap
Bosulif
Braftovi
Brukinsa
Cabometyx
Calquence
Caprelsa
Cometriq
Copiktra
Cotellic
Daurismo
Erivedge
Erleada
Erlotinib Hydrochloride
Everolimus
Exkivity
Farydak
Fotivda
Gavreto
Gefitinib
Gilotrif
Ibrance
Iclusig
Idhifa
Imatinib Mesylate
Imbruvica
Inlyta
Inqovi
Inrebic
Iressa
Jakafi
Jaypirca
Kisqali
Kisqali Femara 200 Dose
Kisqali Femara 400 Dose

Kisqali Femara 600 Dose
Koselugo
Krazati
Lapatinib Ditosylate
Lenalidomide
Lenvima 10 Mg Daily Dose
Lenvima 12Mg Daily Dose
Lenvima 14 Mg Daily Dose
Lenvima 18 Mg Daily Dose
Lenvima 20 Mg Daily Dose
Lenvima 24 Mg Daily Dose
Lenvima 4 Mg Daily Dose
Lenvima 8 Mg Daily Dose
Lonsurf
Lorbrena
Lumakras
Lynparza
Lytgobi
Matulane
Mekinist
Mektovi
Nerlynx
Ninlaro
Nubeqa
Odomzo
Onureg
Orgovyx
Orserdu
Pemazyre
Piqray 200Mg Daily Dose
Piqray 250Mg Daily Dose
Piqray 300Mg Daily Dose
Pomalyst
Qinlock
Retevmo
Revlimid
Rezlidhia
Rozlytrek
Rubraca
Rydapt
Scemblix
Sorafenib
Sprycel
Stivarga

Sunitinib Malate
Tabrecta
Tafinlar
Tagrisso
Talzenna
Tasigna
Tazverik
Tepmetko
Thalomid
Tibsovo
Tretinoin 10Mg Cap
Truseltiq
Tukysa
Turalio
Venclexta
Venclexta Starting Pack
Verzenio
Vitrakvi
Vizimpro
Vonjo
Votrient
Welireg
Xalkori
Xospata
Xpovio
Xpovio 100 Mg Once Weekly
Xpovio 40 Mg Once Weekly
Xpovio 40 Mg Twice Weekly
Xpovio 60 Mg Once Weekly
Xpovio 60 Mg Twice Weekly
Xpovio 80 Mg Once Weekly
Xpovio 80 Mg Twice Weekly
Xtandi
Zejula
Zelboraf
Zolinza
Zydelig
Zykadia

Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:

Criteria for initial approval require BOTH of the following:
1. The 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. Patient has tried appropriate FDA-labeled or compendia-supported therapy that are indicated in NCCN guidelines as first-line therapy OR
            b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication
            OR
            c. 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

Initial criteria continues: see Other Criteria
Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:
        v. ONE of the following:
            a. The requested agent is not Bosulif or Tasigna OR
            b. The requested agent is Bosulif or Tasigna AND ONE of the following:
                1. Patient's medication history indicates use of imatinib OR Sprycel for the requested indication (if applicable) OR
                2. Patient has an intolerance or hypersensitivity to imatinib OR Sprycel OR
                3. Patient has an FDA labeled contraindication to imatinib OR Sprycel OR
                4. CMS approved compendia does not support the use of imatinib OR Sprycel for the requested indication OR
                5. Prescriber has provided information in support of use of Bosulif or Tasigna over imatinib OR Sprycel 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 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. Patient does NOT have any FDA labeled contraindications to the requested agent AND
        iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Prior Authorization Group Description:
Signifor PA
Drug Name(s)
Signifor
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
        iii. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
        iv. Patient has had clinical benefit with the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Initial approval: 6 months for CD, 12 months for all other diagnoses, Renewal approval: 12 months
Other Criteria:

Prior Authorization Group Description:
Sivextro PA
Drug Name(s)
Sivextro
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:
Sodium Oxybate PA
Drug Name(s)
Xyrem
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Somatostatin Analogs PA – Octreotide
Drug Name(s)
Octreotide Acetate
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Somatostatin Analogs PA – Somavert
Drug Name(s)
Somavert
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be 6 months for initial, 12 months for renewal

Other Criteria:

Prior Authorization Group Description:
Sovaldi PA
Drug Name(s)
Sovaldi
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. ONE of the following:
    A. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
    B. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
    C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni 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 TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Substrate Reduction Therapy PA – Miglustat
Drug Name(s)
Miglustat
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 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 GBA gene with two disease-causing alleles AND
2. Prescriber has drawn baseline 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Symdeko PA
Drug Name(s)
Symdeko
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 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 Restrictions:
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:

Prior Authorization Group Description:
Targretin Gel PA
Drug Name(s)
Bexarotene Gel
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for initial approval require BOTH of the following:

1. ONE of the following:
    A. Patient has a diagnosis of stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions 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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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:
Prescriber Restrictions:
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 stage IA or IB cutaneous T-cell lymphoma (CTCL) with cutaneous lesions 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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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

Prior Authorization Group Description:
Teriparatide PA
Drug Name(s)
Forteo
Teriparatide
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
Required Medical Information:
Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:
    A. Postmenopausal with 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:
Prescriber Restrictions:
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, 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

Prior Authorization Group Description:
Tetrabenazine PA
Drug Name(s)
Tetrabenazine
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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) OR the patient's MAOI will be discontinued at least 14 days before starting therapy with the requested agent AND
5. Patient will NOT be using the requested agent in combination with reserpine OR the patient's reserpine will be discontinued at least 20 days before starting therapy with the requested agent

Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Tobramycin neb PA
Drug Name(s)
Tobramycin
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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, inhaled tobramycin) OR
    b. Patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., inhaled aztreonam, 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

Drug is also subject to Part B versus Part D review.
Age Restriction:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Topical Diclofenac 3% Gel PA
Drug Name(s)
Diclofenac Sodium 3% Gel
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 3 months
Other Criteria:

Prior Authorization Group Description:
Topical Retinoids PA – Tazarotene
Drug Name(s)
Tazarotene
Tazorac Cream
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Topical Retinoids PA – Tretinoin
Drug Name(s)
Avita
Tretinoin Cream, Gel
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Trelstar PA
Drug Name(s)
Trelstar Mixject
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
Exclusion Criteria:
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 has been treated with the requested agent within the past 180 days OR
    B. Prescriber states the patient has been 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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Trientine PA
Drug Name(s)
Clovique
Trientine Hydrochloride
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Trikafta PA
Drug Name(s)
Trikafta
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 Restrictions:
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:

Prior Authorization Group Description:

Tymlos PA

Drug Name(s)

Tymlos

Indications:

All FDA-Approved Indications.

Off-Label Uses:

Exclusion Criteria:

Required Medical Information:

Criteria for approval require ALL of the following:

1. Patient (pt) has ONE of the following diagnoses:
    - A. Postmenopausal with 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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Ubrelvy PA
Drug Name(s)
Ubrelvy
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Urea Cycle Disorders PA - Sodium Phenylbutyrate
Drug Name(s)
Sodium Phenylbutyrate
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Viberzi PA
Drug Name(s)
Viberzi
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Voriconazole PA
Drug Name(s)
Voriconazole
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Vosevi PA
Drug Name(s)
Vosevi
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 dosing of the requested agent is within the 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

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Vyndamax PA
Drug Name(s)
Vyndamax
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Vyndaqel PA
Drug Name(s)
Vyndaqel
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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 requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. 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:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Wakix PA
Drug Name(s)
Wakix
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 narcolepsy with cataplexy OR
    B. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND BOTH of the following:
        i. 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:
            1. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR
            2. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR
            3. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate)

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 narcolepsy with cataplexy OR
    B. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:
Patient is 18 years of age or over
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Xgeva PA
Drug Name(s)
Xgeva
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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:
Prescriber Restrictions:
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

Prior Authorization Group Description:
Xolair PA
Drug Name(s)
Xolair
Indications:
All FDA-Approved Indications.
Off-Label Uses:
Exclusion Criteria:
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. If the patient is 6 to less than 12 years of age then BOTH of the following:
            a. Patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL AND
            b. Patient's weight is 20 kg to 150 kg AND
        ii. If the patient is 12 years of age or over then BOTH of the following:
            a. Patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL AND
            b. Patient's weight is 30 kg to 150 kg AND
        iii. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen AND
        iv. Patient has ONE of the following:
            a. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months OR
            b. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR
            c. Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered OR
            d. Patient has a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted AND
        v. ONE of the following:
            a. Patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid (ICS) OR
            b. Patient is currently being treated with the requested agent AND ONE of the following:
                1. Patient is currently being treated with an inhaled corticosteroid that is adequately dosed to control symptoms OR
                2. Patient is currently being treated with a maximally tolerated inhaled corticosteroid OR
            c. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an inhaled corticosteroid AND

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.

Prescriber Restrictions:

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:

vi. ONE of the following:
   a. Patient is currently being treated with ONE of the following:
      1. A long-acting beta-2 agonist (LABA) OR
      2. A leukotriene receptor antagonist (LTRA) OR
      3. A long-acting muscarinic antagonist (LAMA) OR
      4. Theophylline OR
   b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a LABA, LAMA, LTRA, or theophylline 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 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 ALL of the following:
        i. Patient's weight is within the FDA indicated range for their age (i.e., 20 kg to 150 kg for patients age 6 to less than 12 years and 30 kg to 150 kg for patients 12 years of age or over) AND
        ii. Patient has had clinical benefit with the requested agent AND
        iii. ONE of the following:
            a. Patient is currently being treated with standard therapy (such as a combination of an ICS, LABA, LAMA, LTRA, theophylline, oral corticosteroid or an oral beta-2 agonist tablet) OR
            b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard 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 AND
3. The requested agent will NOT be used 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

Prior Authorization Group Description:
Xywav PA
Drug Name(s)
Xywav
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 a diagnosis of idiopathic hypersomnia OR
    D. Patient has another indication that is supported in CMS approved compendia for the requested agent

Age Restriction:
For diagnosis of narcolepsy with cataplexy, patient is 7 years of age or over. For diagnosis of narcolepsy with excessive daytime sleepiness, patient is 7 years of age or over. For diagnosis of idiopathic hypersomnia, patient is 18 years of age or over.
Prescriber Restrictions:
Coverage Duration:
Approval will be for 12 months
Other Criteria:

Prior Authorization Group Description:
Zepatier PA
Drug Name(s)
Zepatier
Indications:
All Medically-Accepted Indications.
Off-Label Uses:
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 dosing of the requested agent is within the 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 has been treated with the requested agent within the past 90 days OR
    B. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
    C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni 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 TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:
Prescriber Restrictions:
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:

Prior Authorization Group Description:
Zokinvy PA
Drug Name(s)
Zokinvy
Indications:
All FDA-Approved Indications.
Off-Label Uses:
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 Restrictions:
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: