

2023 PRIOR AUTHORIZATION CRITERIA

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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:

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 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 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

Caplyta

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

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:

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 18 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:
 - 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 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

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

Lorazepam 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. 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 – 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
 - 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 diagnosis of ulcerative colitis

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

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 plaque psoriasis or psoriatic arthritis

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 - 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:

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 – 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:

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:

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:

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:

Pending CMS Review

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

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

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 – 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)

Esbriet Cap

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:

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)

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., Betaseron, Copaxone, dimethyl fumarate) 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 – 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, angiotensin-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, angiotensin-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

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

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)

Hetlioz

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. 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)

Benzotropine Mesylate

Clemastine Fumarate

Cyproheptadine Hydrochloride

Dicyclomine Hydrochloride

Diphenoxylate Hydrochloride/Atropine Sulfate

Hydroxyzine Hydrochloride

Promethazine Hydrochloride

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:

1. Patient has ONE of the following diagnoses:

- A. Actinic keratosis OR
- B. Superficial basal cell carcinoma OR
- C. External genital and/or perianal warts/condyloma acuminata OR
- D. Squamous cell carcinoma OR
- E. Basal cell carcinoma OR
- F. Another indication that is supported in CMS approved compendia for the requested agent

Age Restriction:

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:

Injectable Oncology PA

Drug Name(s)

Margenza

Nelarabine

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:

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:

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 BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient is currently receiving the following standard of care background therapy with the requested agent
 - A. A maximally tolerated dose of ACE inhibitor, ARB, or a combination medication containing an ACE or ARB AND
 - B. Antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1 RA)

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 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 agentAND
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:

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

Age Restriction:

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:

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

Age Restriction:

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:

1. 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
2. Patient will NOT be using the requested agent in combination with Sivextro (tedizolid) for the same infection AND
 3. The requested dose is within FDA labeled dosing for the requested indication

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:

1. Patient is younger than 30 years of age AND ONE of the following:
 - A. Patient has a diagnosis of moderate to severe dementia of the Alzheimer's type OR
 - B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restriction:

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:

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:

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:

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., 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:

Movantik PA

Drug Name(s)

Movantik

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

Age Restriction:

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 – Glatiramer

Drug Name(s)

Copaxone

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:

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:

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:

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:

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:

1. ONE of the following:
 - A. BOTH of the following:
 - i. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
 - ii. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD) OR
 - B. BOTH of the following:
 - i. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND
 - ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans OR
 - C. BOTH of the following:
 - i. Patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND
 - ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of ONE of the following:
 - A. Idiopathic pulmonary fibrosis (IPF) OR
 - B. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) OR
 - C. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**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:

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 – 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:

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:

1. ONE of the following:

A. Patient has a diagnosis of chronic hepatitis B AND BOTH of the following:

- i. The chronic hepatitis B infection has been confirmed by serological markers AND
- ii. Patient has NOT been administered the requested agent for more than 48 weeks for the treatment of chronic hepatitis B OR

B. BOTH of the following:

- i. Patient has a diagnosis of chronic hepatitis C confirmed by serological markers AND
- ii. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling 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

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 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-aqcg, 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 $75 \times 10^9/L$ 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 $0.5 \times 10^9/L$ OR
 - ii. Platelets less than $20 \times 10^9/L$ OR
 - iii. Reticulocytes less than 1% corrected [percentage of actual hematocrit (Hct) to normal Hct] or reticulocyte count less than $60 \times 10^9/L$ 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 $50 \times 10^9/L$ 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 $90 \times 10^9/L$ 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 $20 \times 10^9/L$ 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:

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 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 – 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:

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:

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
- 3. 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
- 4. 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:

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:

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

Bexarotene Cap

Bosulif

Braftovi

Brukinsa

Cabometyx

Calquence

Caprelsa

Cometriq

Copiktra

Cotellic

Daurismo

Erivedge

Erleada

Erlotinib Hydrochloride

Everolimus

Exkivity

Farydak

Fotivda

Gavreto

Gilotrif

Ibrance

Iclusig

Idhifa

Imatinib Mesylate

Imbruvica

Inlyta

Inqovi

Inrebic

Iressa

Jakafi
Kisqali
Kisqali Femara 200 Dose
Kisqali Femara 400 Dose
Kisqali Femara 600 Dose
Koselugo
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
Matulane
Mekinist
Mektovi
Nerlynx
Ninlaro
Nubeqa
Odomzo
Onureg
Orgovyx
Pemazyre
Piqray 200Mg Daily Dose
Piqray 250Mg Daily Dose
Piqray 300Mg Daily Dose
Pomalyst
Qinlock
Retevmo

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

- i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND
- ii. Patient has had clinical benefit with the requested agent

Age Restriction:

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:

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:

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:

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 Retinoids PA – Tazarotene

Drug Name(s)

Tazarotene

Tazorac

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 is postmenopausal with a diagnosis of osteoporosis AND BOTH of the following:
 - A. Patient'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. Patient is at a very high fracture risk as defined by ONE of the following:
 - a. Patient had a recent fracture (within the past 12 months) OR
 - b. Patient had fractures while on FDA approved osteoporosis therapy OR
 - c. Patient has had multiple fractures OR
 - d. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
 - e. Patient has a very low T-score (less than -3.0) OR
 - f. Patient is at high risk for falls or has a history of injurious falls OR
 - g. 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
 - ii. ONE of the following:
 - a. Patient has tried and had an inadequate response to a bisphosphonate OR
 - b. Patient has an intolerance or hypersensitivity to a bisphosphonate OR
 - c. Patient has an FDA labeled contraindication to a bisphosphonate AND
2. 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., teriparatide) for the requested indication AND
3. The requested dose is within FDA labeled dosing for the requested indication AND
4. 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:

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:

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:

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:

Pending CMS Review

Prior Authorization Group Description:

Xifaxan PA

Drug Name(s)

Xifaxan

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 ONE of the following:

- a. A diagnosis of irritable bowel syndrome with diarrhea (IBS-D) OR
- b. A diagnosis of hepatic encephalopathy [reduction in risk of overt hepatic encephalopathy (HE) recurrence] OR
- c. BOTH of the following:
 - i. A diagnosis of traveler's diarrhea (TD) AND
 - ii. The traveler's diarrhea is caused by noninvasive strains of Escherichia coli

Age Restriction:

For diagnosis of traveler's diarrhea (TD), 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:

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, Fasentra, 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, Fasentra, 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: