

2023 PRIOR AUTHORIZATION CRITERIA

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Prior Authorization Group Description:

Acthar Gel PA

Drug Name(s)

Acthar

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 infantile spasm OR
- b. Patient has a diagnosis of nephrotic syndrome AND ONE of the following:
 - i. Patient has failed a conventional agent (i.e., prednisone, tacrolimus) for the requested indication OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a conventional agent OR
- c. Patient has a diagnosis of multiple sclerosis AND ALL of the following:
 - i. Patient is experiencing an acute exacerbation AND
 - ii. If indicated, there is evidence of a claim that the patient is currently being treated with a disease modifying drug (DMD) within the past 90 days [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, Gilenya, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia] to control disease progression OR has an intolerance, FDA labeled contraindication, or hypersensitivity to a DMD AND
 - iii. ONE of the following:
 - 1. Patient has failed corticosteroid therapy within the last 30 days OR
 - 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR

Criteria continues: see Other Criteria

Age Restriction:

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

Prescriber Restrictions:**Coverage Duration:**

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

Other Criteria:

- d. Patient has a diagnosis of rheumatic disorder (e.g., ankylosing spondylitis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis) AND ALL of the following:
 - i. The requested agent will be used as adjunct therapy for short-term administration (to tide the patient over an acute episode or exacerbation) AND

- ii. There is evidence of a claim that the patient is currently being treated with a conventional agent within the past 90 days [e.g., DMARD (methotrexate, leflunomide), biologics (Humira)] to control disease progression AND
- iii. ONE of the following:
 - 1. Patient has failed corticosteroid therapy within the last 30 days
OR
 - 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR
- e. Patient has a diagnosis of systemic lupus erythematosus (SLE) disease AND the patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
- f. Patient has another FDA approved indication AND ONE of the following:
 - i. Patient has failed corticosteroid therapy within the last 30 days OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR
- g. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
 - i. Patient has failed corticosteroid therapy within the last 30 days OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) AND
- 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

Prior Authorization Group Description:

Actimmune PA

Drug Name(s)

Actimmune

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Acyclovir Topical PA

Drug Name(s)

Acyclovir

Zovirax

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:

Adakveo PA

Drug Name(s)

Adakveo

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 sickle cell disease AND
2. Patient is using the requested agent to reduce the frequency of vasoocclusive crises of sickle cell disease AND
3. ONE of the following
 - A. Patient has tried and had an inadequate response to maximally tolerated dose of hydroxyurea OR
 - B. Patient has an intolerance or hypersensitivity to hydroxyurea OR
 - C. Patient has an FDA labeled contraindication to hydroxyurea AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of sickle cell disease AND
3. Patient is using the requested agent to reduce the frequency of vasoocclusive crises of sickle cell disease AND
4. Patient has had clinical benefit with the requested agent AND
5. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Adbry PA

Drug Name(s)

Adbry

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 moderate-to-severe atopic dermatitis AND BOTH of the following:
 - A. ONE of the following:
 - i. Patient has tried and failed a topical steroid (e.g., triamcinolone) OR
 - ii. Patient has an intolerance or hypersensitivity to a topical steroid OR
 - iii. Patient has an FDA labeled contraindication to a topical steroid AND
 - B. ONE of the following:
 - i. Patient has tried and failed a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR
 - ii. Patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor OR
 - iii. Patient has an FDA labeled contraindication to a topical calcineurin inhibitor AND
2. Patient will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Cibinqo, Opzelura, Dupixent, Rinvoq) 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 moderate-to-severe atopic dermatitis 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 or a JAK inhibitor for the requested indication (e.g., Cibinqo, Opzelura, Dupixent, Rinvoq) 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., allergist, dermatologist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Aimovig PA

Drug Name(s)

Aimovig

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
 2. The requested agent is being used for migraine prophylaxis AND
 3. Patient has 4 migraine headaches or more per month AND
 4. ONE of the following:
 - A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
 - B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agentOR
 - C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agent
- AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for migraine prophylaxis AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Ajovy PA

Drug Name(s)

Ajovy

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for migraine prophylaxis AND
3. Patient has 4 migraine headaches or more per month AND
4. ONE of the following:
 - A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
 - B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agentOR
 - C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agentAND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for migraine prophylaxis AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Alosetron PA

Drug Name(s)

Alosetron Hydrochloride

Lotronex

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 - Aralast/Prolastin-C/Zemaira

Drug Name(s)

Aralast Np

Prolastin-C

Zemaira

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:

Alpha-1-Proteinase Inhibitor PA – Glassia

Drug Name(s)

Glassia

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:

Amantadine ER PA – Gocovri

Drug Name(s)

Gocovri

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 Parkinson's disease AND
2. ONE of the following:
 - A. The requested agent will be used for the treatment of dyskinesia OR
 - B. The requested agent will be used for the adjunctive treatment in patients experiencing "off" episodes AND
3. The requested agent will be used in combination with levodopa-based therapy

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:

Amantadine ER PA - Osmolex ER

Drug Name(s)

Osmolex Er

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. ONE of the following:

A. Patient has a diagnosis of Parkinson's disease OR

B. BOTH of the following:

i. Patient has a diagnosis of drug-induced extrapyramidal reaction AND

ii. Prescriber has assessed and adjusted, if applicable, any medications known to cause extrapyramidal symptoms

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:

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 – Aveed

Drug Name(s)

Aveed

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's sex is male with a diagnosis of primary or secondary (hypogonadotropic) hypogonadism AND
2. 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 for 12 months

Other Criteria:

Prior Authorization Group Description:

Androgen Injectable PA - testosterone cypionate

Drug Name(s)

Depo-Testosterone

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 Injectable PA – Xyosted

Drug Name(s)

Xyosted

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 male with primary or secondary (hypogonadotropic) hypogonadism AND

2. Patient's sex is male with 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 for 12 months

Other Criteria:

Prior Authorization Group Description:

Androgen Oral PA

Drug Name(s)

Methitest

Methyltestosterone

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. Patient has ONE of the following diagnoses:

- A. Patient's sex is male with cryptorchidism OR
- B. Patient's sex is male with hypogonadism OR
- C. Patient's sex is male and is an adolescent with delayed puberty OR
- D. Patient's sex is female with metastatic/inoperable breast cancer AND

2. If the patient's sex is male, ONE of the following:

- A. Patient is NOT currently receiving testosterone replacement therapy AND has ONE of the following pretreatment levels:
 - i. Total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR
 - ii. Free serum testosterone level that is below the testing laboratory's lower limit of the normal range OR
- B. Patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels:
 - i. Total serum testosterone level that is within OR below the testing laboratory's lower limit of the normal range OR is less than 300 ng/dL OR
 - ii. Free serum testosterone level is within OR below the testing laboratory's normal range AND

3. ONE of the following:

- A. Patient will NOT be using the requested agent in combination with another androgen or anabolic steroid OR
- B. Prescriber has provided information in support of therapy with more than one agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

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

Other Criteria:

Prior Authorization Group Description:

Androgen Topical PA

Drug Name(s)

Androderm

Androgel

Fortesta

Natesto

Testim

Testosterone

Testosterone Pump

Testosterone Topical Solution

Vogelxo

Vogelxo 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)

Abilify
Abilify Mycite
Abilify Mycite Maintenance Kit
Abilify Mycite Starter Kit
Aripiprazole
Aripiprazole Odt
Asenapine Maleate SI
Chlorpromazine Hydrochloride
Clozapine
Clozapine Odt
Clozaril
Fanapt
Fanapt Titration Pack
Fluphenazine Decanoate
Fluphenazine Hydrochloride
Geodon
Haldol Decanoate 100
Haldol Decanoate 50
Haloperidol
Haloperidol Decanoate
Haloperidol Lactate
Invega
Loxapine
Lybalvi
Molindone Hydrochloride
Olanzapine
Olanzapine Odt
Olanzapine/Fluoxetine
Paliperidone Er
Perphenazine
Quetiapine Fumarate
Quetiapine Fumarate Er
Rexulti
Risperdal
Risperidone
Risperidone Odt
Saphris
Secuado
Seroquel
Seroquel Xr
Symbyax

Thioridazine Hcl
Thiothixene
Trifluoperazine Hcl
Versacloz
Ziprasidone Mesylate
Zyprexa
Zyprexa Relprevv
Zyprexa Zydis

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:

Aptensio XR PA

Drug Name(s)

Aptensio Xr

Methylphenidate Hydrochloride Er

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

Prescriber Restrictions:**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:

Arikayce PA

Drug Name(s)

Arikayce

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 Mycobacterium avium complex (MAC) lung disease AND
2. Patient has not achieved negative sputum cultures despite at least 6 consecutive months of treatment with standard combination antibiotic therapy for MAC lung disease [e.g., standard combination may include a macrolide (clarithromycin, azithromycin), rifampin, and ethambutol] AND
3. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), rifampin, and ethambutol]

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Mycobacterium avium complex (MAC) lung disease AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will continue treatment with a combination antibiotic therapy for MAC lung disease with the requested agent [e.g., combination may include a macrolide (clarithromycin, azithromycin), rifampin, and ethambutol]

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Armodafinil PA

Drug Name(s)

Armodafinil

Nuvigil

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:

Asceniv PA

Drug Name(s)

Asceniv

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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:

- i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

J. Refractory pemphigus vulgaris AND ONE of the following:

- i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR

2. ONE of the following:

- A. Patient has another FDA labeled indication for the requested agent OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

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

Prior Authorization Group Description:

Atopic Dermatitis PA – Eucrisa

Drug Name(s)

Eucrisa

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 atopic dermatitis AND
2. 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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Atopic Dermatitis PA – Pimecrolimus

Drug Name(s)

Elidel

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)

Protopic

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

Mepron

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

1. Patient has a diagnosis of mild-to-moderate *Pneumocystis jirovecii* pneumonia OR
2. Patient is using the requested agent for prevention of *Pneumocystis jirovecii* pneumonia AND

ii. ONE of the following:

1. Patient has an intolerance or hypersensitivity to trimethoprim/sulfamethoxazole (TMP/SMX) OR
2. Patient has an FDA labeled contraindication to trimethoprim/sulfamethoxazole (TMP/SMX) OR

B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Auryxia PA

Drug Name(s)

Auryxia

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

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

Required Medical Information:

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Austedo PA

Drug Name(s)

Austedo

Austedo Xr

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. ONE of the following:

A. Patient has a diagnosis of chorea associated with Huntington's disease AND BOTH of the following:

i. ONE of the following:

1. Patient does NOT have a current diagnosis of depression OR
2. Patient has a current diagnosis of depression and is being treated for depression AND

ii. ONE of the following:

1. Patient does NOT have a diagnosis of passive suicidal ideation OR
2. Patient has a diagnosis of passive suicidal ideation and must NOT be actively suicidal OR

B. Patient has a diagnosis of tardive dyskinesia AND ONE of the following:

i. Prescriber has reduced the dose of or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) OR

ii. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate AND

2. Patient will NOT be using the requested agent in combination with a monoamine oxidase inhibitor (MAOI) OR the patient's MAOI will be discontinued at least 14 days before starting therapy with the requested agent AND

3. 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:

Azstarys PA

Drug Name(s)

Azstarys

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:

Belsomra PA

Drug Name(s)

Belsomra

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benign Prostatic Hyperplasia PA – Tadalafil

Drug Name(s)

Cialis

Tadalafil 2.5Mg, 5Mg

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

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

Required Medical Information:

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of benign prostatic hyperplasia (BPH) AND
2. ONE of the following:
 - a. Patient has tried and had an inadequate response to two alpha blocker agents (e.g., terazosin, doxazosin, tamsulosin) OR
 - b. Patient has an intolerance or hypersensitivity to two alpha blocker agents (e.g., terazosin, doxazosin, tamsulosin) OR
 - c. Patient has an FDA labeled contraindication to two alpha blocker agents (e.g., terazosin, doxazosin, tamsulosin)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benlysta IV PA

Drug Name(s)

Benlysta IV

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
 - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
 - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
 - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
2. Patient will NOT be using the requested agent in combination with another biologic agent AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

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

Age Restriction:

For diagnosis of active systemic lupus erythematosus (SLE) disease, patient is 5 years of age or over. For diagnosis of active lupus nephritis (LN), patient is 5 years of age or over.

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benlysta SC PA

Drug Name(s)

Benlysta SC

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
 - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
 - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
 - i. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
2. Patient will NOT be using the requested agent in combination with another biologic agent AND
3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. ONE of the following:
 - a. Patient has diagnosis of active systemic lupus erythematosus (SLE) disease AND the following:
 - i. Patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
 - b. Patient has a diagnosis of active lupus nephritis (LN) AND the following:
 - 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 - Chlordiazepoxide

Drug Name(s)

Chlordiazepoxide Hydrochloride

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

b. Prescriber states the patient is currently being treated with the requested agent AND

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

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Anxiety disorder AND ONE of the following:

1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR

2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR

3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR

b. Alcohol withdrawal OR

c. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benzodiazepines PA – Chlordiazepoxide /amitriptyline

Drug Name(s)

Chlordiazepoxide/Amitriptyline

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. ALL of the following:

i. Patient has ONE of the following diagnoses:

- a. Moderate to severe depression with moderate to severe anxiety 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. ONE of the following:

- a. Patient has not taken a monoamine oxidase inhibitor (MAOI) in the past 30 days OR
- b. Patient has taken an MAOI in the past 30 days AND will discontinue at least 14 days prior to starting the requested agent 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:

Benzodiazepines PA – Clobazam

Drug Name(s)

Clobazam

Onfi

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

Tranxene T

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND

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

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

- a. Seizure disorder OR
- b. Anxiety disorder AND ONE of the following:
 - 1) Patient has tried and has an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
 - 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR
 - 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR
- c. Alcohol withdrawal OR
- d. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benzodiazepines PA – Diazepam

Drug Name(s)

Diazepam

Diazepam Intensol

Valium

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 – Estazolam

Drug Name(s)

Estazolam

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 insomnia 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:

Benzodiazepines PA – Flurazepam

Drug Name(s)

Flurazepam Hcl

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 insomnia 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:

Benzodiazepines PA – Lorazepam

Drug Name(s)

Ativan

Lorazepam

Loreev Xr

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND

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

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Anxiety disorder AND ONE of the following:

- 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
- 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR
- 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benzodiazepines PA – Oxazepam

Drug Name(s)

Oxazepam

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND

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

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Anxiety disorder AND ONE of the following:

- 1) Patient has tried and had an inadequate response to a formulary selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI) OR
- 2) Patient has an intolerance or hypersensitivity to a formulary SSRI or SNRI OR
- 3) Patient has an FDA labeled contraindication to a formulary SSRI or SNRI OR

b. Alcohol withdrawal OR

c. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Benzodiazepines PA – Sympazan

Drug Name(s)

Sympazan

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR

b. Prescriber states the patient is currently being treated with the requested agent AND

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

B. BOTH of the following:

i. Patient has ONE of the following diagnoses:

a. Seizure disorder OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Bethkis PA

Drug Name(s)

Bethkis

Tobramycin (Bethkis)

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:

Biologic Immunomodulators PA – Actemra

Drug Name(s)

Actemra

Actemra Actpen

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel, Humira, Xeljanz tablets, or Xeljanz oral solution) is required for diagnosis of juvenile idiopathic arthritis

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

NO preferred agent is required for diagnoses of giant cell arteritis, systemic sclerosis-associated interstitial lung disease (SSc-ILD), or cytokine release syndrome

Prior Authorization Group Description:

Biologic Immunomodulators PA – Avsola

Drug Name(s)

Avsola

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira, Skyrizi, and Stelara) is required for diagnosis of adult Crohn's disease

Use of TWO preferred agents (Humira and Stelara) is required for diagnosis of adult ulcerative colitis

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

NO preferred agent is required for diagnosis of adult fistulizing Crohn's disease

Prior Authorization Group Description:

Biologic Immunomodulators PA – Cimzia

Drug Name(s)

Cimzia

Cimzia Starter Kit

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira, Skyrizi, and Stelara) is required for diagnosis of adult Crohn's disease

NO prerequisites are required for diagnosis of non-radiographic Axial Spondyloarthritis

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 – Ilumya

Drug Name(s)

Ilumya

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Prior Authorization Group Description:

Biologic Immunomodulators PA – Inflectra

Drug Name(s)

Inflectra

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira, Skyrizi, and Stelara) is required for diagnosis of adult Crohn's disease

Use of TWO preferred agents (Humira and Stelara) is required for diagnosis of adult ulcerative colitis

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

NO preferred agent is required for diagnosis of adult fistulizing Crohn's disease

Prior Authorization Group Description:

Biologic Immunomodulators PA – Kevzara

Drug Name(s)

Kevzara

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

NO preferred agent is required for diagnosis of polymyalgia rheumatica

Prior Authorization Group Description:

Biologic Immunomodulators PA – Kineret

Drug Name(s)

Kineret

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

NO preferred agent is required for diagnoses of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Prior Authorization Group Description:

Biologic Immunomodulators PA – Olumiant

Drug Name(s)

Olumiant

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

NO preferred agent is required for diagnosis of alopecia areata

Prior Authorization Group Description:

Biologic Immunomodulators PA – Orencia

Drug Name(s)

Orencia

Orencia Clickject

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel, Humira, Xeljanz tablets, or Xeljanz oral solution) is required for diagnosis of juvenile idiopathic arthritis

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of psoriatic arthritis

NO preferred agent is required for diagnosis of prophylaxis of acute graft vs host disease

Prior Authorization Group Description:

Biologic Immunomodulators PA – Remicade

Drug Name(s)

Infliximab

Remicade

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira, Skyrizi, and Stelara) is required for diagnosis of adult Crohn's disease

Use of TWO preferred agents (Humira and Stelara) is required for diagnosis of adult ulcerative colitis

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

NO preferred agent is required for diagnosis of adult fistulizing Crohn's disease

Prior Authorization Group Description:

Biologic Immunomodulators PA – Renflexis

Drug Name(s)

Renflexis

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR
 - ii. The request is for an FDA labeled indication that is not covered by preferred biologic immunomodulator agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira, Skyrizi, and Stelara) is required for diagnosis of adult Crohn's disease

Use of TWO preferred agents (Humira and Stelara) is required for diagnosis of adult ulcerative colitis

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

NO preferred agent is required for diagnosis of adult fistulizing Crohn's disease

Prior Authorization Group Description:

Biologic Immunomodulators PA – Riabni

Drug Name(s)

Riabni

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. ALL of the following:

A. ONE of the following:

i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:

a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR

b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR

c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR

ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND

B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND

C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND

D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

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 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 been previously approved for the requested agent through the plan's Prior Authorization criteria AND
 - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
 - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
 - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

Prior Authorization Group Description:

Biologic Immunomodulators PA – Rinvoq

Drug Name(s)

Rinvoq

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

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

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

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

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

Prior Authorization Group Description:

Biologic Immunomodulators PA – Rituxan

Drug Name(s)

Rituxan

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. ALL of the following:

A. ONE of the following:

i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:

a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR

b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR

c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR

ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND

B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND

C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND

D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

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 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 been previously approved for the requested agent through the plan's Prior Authorization criteria AND
 - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
 - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
 - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

Prior Authorization Group Description:

Biologic Immunomodulators PA - Rituxan Hycela

Drug Name(s)

Rituxan Hycela

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent OR
 - C. ALL of the following:
 - i. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND
 - ii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
 - iii. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

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 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 been previously approved for the requested agent through the plan's Prior Authorization criteria AND
 - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND

- iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
- iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

There are no preferred agents required for Rituxan Hycela

Prior Authorization Group Description:

Biologic Immunomodulators PA – Ruxience

Drug Name(s)

Ruxience

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. ALL of the following:

A. ONE of the following:

i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:

a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR

b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR

c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR

ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND

B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND

C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND

D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

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 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 been previously approved for the requested agent through the plan's Prior Authorization criteria AND
 - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
 - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
 - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

Prior Authorization Group Description:

Biologic Immunomodulators PA – Siliq

Drug Name(s)

Siliq

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

Prior Authorization Group Description:

Biologic Immunomodulators PA – Simponi

Drug Name(s)

Simponi

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Humira and Stelara) is required for diagnosis of ulcerative colitis

Prior Authorization Group Description:

Biologic Immunomodulators PA - Simponi Aria

Drug Name(s)

Simponi Aria

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Enbrel and Humira) is required for diagnosis of rheumatoid arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of psoriatic arthritis

Use of TWO preferred agents (Cosentyx, Enbrel, or Humira) is required for diagnosis of ankylosing spondylitis

Use of TWO preferred agents (Enbrel and Humira) is required for diagnosis of juvenile idiopathic arthritis

Prior Authorization Group Description:

Biologic Immunomodulators PA – Skyrizi

Drug Name(s)

Skyrizi

Skyrizi Pen

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
 - D. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
 - E. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
 - F. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Use of ONE conventional prerequisite agent is required for diagnoses of Crohn's disease, plaque psoriasis, or psoriatic arthritis

Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine

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

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

Prior Authorization Group Description:

Biologic Immunomodulators PA – Sotyktu

Drug Name(s)

Sotyktu

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

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 – Taltz

Drug Name(s)

Taltz

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 diagnosis is indicated for preferred biologic immunomodulator agent(s) AND ONE of the following:
 - a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR
 - b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR
 - c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) 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 TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of psoriatic arthritis

For patients 18 years of age or over, use of TWO preferred agents (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, or Tremfya) is required for diagnosis of plaque psoriasis

For patients between 12 and less than 18 years of age, use of TWO preferred agents (Cosentyx, Enbrel, or Stelara) is required for diagnosis of plaque psoriasis

For patients between 6 and less than 12 years of age, use of ONE preferred agent (Cosentyx, Enbrel, or Stelara) is required for diagnosis of plaque psoriasis

Use of TWO preferred agents (Cosentyx, Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of ankylosing spondylitis

Use of ONE preferred agent (Cosentyx or Rinvoq) is required for diagnosis of non-radiographic Axial Spondyloarthritis

Prior Authorization Group Description:

Biologic Immunomodulators PA – Tremfya

Drug Name(s)

Tremfya

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR
 - D. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR
 - E. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR
 - F. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis or plaque psoriasis

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

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

Prior Authorization Group Description:

Biologic Immunomodulators PA - Truxima

Drug Name(s)

Truxima

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. ALL of the following:

A. ONE of the following:

i. Patient has a diagnosis of rheumatoid arthritis AND ONE of the following:

a. Patient's medication history indicates use of preferred biologic immunomodulator agent(s) OR

b. Patient has an intolerance or hypersensitivity to preferred biologic immunomodulator agent(s) OR

c. Patient has an FDA labeled contraindication to preferred biologic immunomodulator agent(s) OR

ii. Patient has another FDA labeled indication or an indication that is supported in CMS approved compendia AND

B. Patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) and has begun therapy, if appropriate, prior to receiving the requested agent AND

C. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND

D. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

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 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 been previously approved for the requested agent through the plan's Prior Authorization criteria AND
 - ii. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
 - iii. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
 - iv. Patient does NOT have any FDA labeled limitation(s) of use for the requested agent that is not otherwise supported in NCCN guidelines

Use of TWO preferred agents (Enbrel, Humira, Rinvoq, Xeljanz tablets, or Xeljanz XR) is required for diagnosis of rheumatoid arthritis

ALL other diagnoses do NOT require any preferred agents

Prior Authorization Group Description:

Biologic Immunomodulators PA - Xeljanz Solution

Drug Name(s)

Xeljanz Solution

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. ONE of the following:
 - i. Patient's medication history indicates use of preferred TNF agent(s) OR
 - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
 - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Use of ONE preferred TNF (Enbrel or Humira) is required for diagnosis of juvenile idiopathic arthritis

Prior Authorization Group Description:

Biologic Immunomodulators PA - Xeljanz Tablet

Drug Name(s)

Xeljanz Tablet

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. ONE of the following:
 - i. Patient's medication history indicates use of preferred TNF agent(s) OR
 - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
 - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

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

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

Prior Authorization Group Description:

Biologic Immunomodulators PA - Xeljanz XR

Drug Name(s)

Xeljanz Xr

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. ONE of the following:
 - i. Patient's medication history indicates use of preferred TNF agent(s) OR
 - ii. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR
 - iii. Patient has an FDA labeled contraindication to preferred TNF agent(s) AND
3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND
4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

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

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

Prior Authorization Group Description:

Bivigam/Flebogamma/Gammaplex/Octagam/Privigen PA

Drug Name(s)

Bivigam

Flebogamma Dif

Gammaplex

Octagam

Privigen

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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:

- i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

J. Refractory pemphigus vulgaris AND ONE of the following:

- i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR

2. ONE of the following:

- A. Patient has another FDA labeled indication for the requested agent OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

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

Prior Authorization Group Description:

Budesonide Oral ER PA – Entocort

Drug Name(s)

Budesonide

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Budesonide Oral ER PA – Ortikos

Drug Name(s)

Ortikos

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

Uceris

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:

Bylvay PA

Drug Name(s)

Bylvay

Bylvay (Pellets)

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 progressive familial intrahepatic cholestasis (PFIC) AND
2. The requested agent will be used to treat pruritus AND
3. 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:

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

Camzyos PA

Drug Name(s)

Camzyos

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 symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) AND
2. The requested agent will be used to improve functional capacity and symptoms

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:

Carglumic PA

Drug Name(s)

Carbaglu

Carglumic Acid

Indications:

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

Off-Label Uses:

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

Exclusion Criteria:**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:

Cayston PA

Drug Name(s)

Cayston

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

Age Restriction:**Prescriber Restrictions:****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:

Chorionic Gonadotropin PA

Drug Name(s)

Chorionic Gonadotropin

Novarel

Pregnyl W/Diluent Benzyl Alcohol/NaCl

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

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

Required Medical Information:

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of prepubertal cryptorchidism not due to anatomic obstruction OR

B. Patient's sex is male, with a diagnosis of hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency) AND BOTH of the following:

i. Patient has a measured current or pretreatment total serum testosterone level that is below the testing laboratory's lower limit of the normal range or is less than 300 ng/dL OR a free serum testosterone level that is below the testing laboratory's lower limit of the normal range AND

ii. Patient has measured luteinizing hormone (LH) AND follicle-stimulating hormone (FSH) levels that are at (low-normal) or below the testing laboratory's normal range OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Cibinqo PA

Drug Name(s)

Cibinqo

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 moderate-to-severe atopic dermatitis AND BOTH of the following:
 - A. ONE of the following:
 - i. Patient has tried and failed a topical steroid (e.g., triamcinolone) OR
 - ii. Patient has an intolerance or hypersensitivity to a topical steroid OR
 - iii. Patient has an FDA labeled contraindication to a topical steroid AND
 - B. ONE of the following:
 - i. Patient has tried and failed a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR
 - ii. Patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor OR
 - iii. Patient has an FDA labeled contraindication to a topical calcineurin inhibitor AND
2. Patient will NOT be using the requested agent in combination with biologic immunomodulator agents, other JAK inhibitors, OR other immunosuppressants

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 moderate-to-severe atopic dermatitis AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with biologic immunomodulator agents, other JAK inhibitors, OR other immunosuppressants

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Cinacalcet PA

Drug Name(s)

Cinacalcet Hydrochloride

Sensipar

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:

Cinqair PA

Drug Name(s)

Cinqair

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

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

Initial criteria continues: see Other Criteria

Age Restriction:

Patient is 18 years of age or over

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Fasenra, Nucala) for the requested indication AND
6. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
7. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype AND
3. Patient has had clinical benefit with the requested agent AND
4. ONE of the following:
 - A. Patient is currently being treated with standard therapy [e.g., ICS, LABA, LTRA, LAMA, theophylline] OR
 - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy AND
5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Fasenra, Nucala) for the requested indication AND
6. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
7. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:

Colony Stimulating Factors PA – Fulphila

Drug Name(s)

Fulphila

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Fylnetra

Drug Name(s)

Fylnetra

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Granix

Drug Name(s)

Granix

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Leukine

Drug Name(s)

Leukine

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Neulasta

Drug Name(s)

Neulasta

Neulasta Onpro Kit

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:
 - i. Patient has an FDA labeled or CMS compendia supported indication for the requested agent that is not indicated for ONE preferred agent OR
 - ii. Patient has tried and had an inadequate response to ONE preferred agent OR
 - iii. Patient has an intolerance or hypersensitivity to ONE preferred agent OR
 - iv. Patient has an FDA labeled contraindication to ONE preferred agent OR
 - v. Prescriber has provided information in support of the use of the non-preferred agent over ONE preferred agent

Preferred agent(s) are Fulphila, Fylnetra, Granix, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Neupogen

Drug Name(s)

Neupogen

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:
 - i. Patient has an FDA labeled or CMS compendia supported indication for the requested agent that is not indicated for ONE preferred agent OR
 - ii. Patient has tried and had an inadequate response to ONE preferred agent OR
 - iii. Patient has an intolerance or hypersensitivity to ONE preferred agent OR
 - iv. Patient has an FDA labeled contraindication to ONE preferred agent OR
 - v. Prescriber has provided information in support of the use of the non-preferred agent over ONE preferred agent

Preferred agent(s) are Fulphila, Fylnetra, Granix, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Nivestym

Drug Name(s)

Nivestym

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Nyvepria

Drug Name(s)

Nyvepria

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Releuko

Drug Name(s)

Releuko

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Rolvedon

Drug Name(s)

Rolvedon

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Udenyca

Drug Name(s)

Udenyca

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Zarxio

Drug Name(s)

Zarxio

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Colony Stimulating Factors PA – Ziextenzo

Drug Name(s)

Ziextenzo

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Concerta PA

Drug Name(s)

Concerta

Methylphenidate Hydrochloride Er (Concerta)

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:

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:

Cortrophin Gel PA

Drug Name(s)

Cortrophin

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 nephrotic syndrome AND ONE of the following:
 - i. Patient has failed a conventional agent (i.e., prednisone, tacrolimus) for the requested indication OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a conventional agent OR
- b. Patient has a diagnosis of multiple sclerosis AND ALL of the following:
 - i. Patient is experiencing an acute exacerbation AND
 - ii. If indicated, there is evidence of a claim that the patient is currently being treated with a disease modifying drug (DMD) within the past 90 days [e.g., Aubagio, Avonex, Bafiertam, Betaseron, dimethyl fumarate (e.g., Tecfidera), Extavia, Gilenya, glatiramer (e.g., Copaxone, Glatopa), Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia] to control disease progression OR has an intolerance, FDA labeled contraindication, or hypersensitivity to a DMD AND
 - iii. ONE of the following:
 - 1. Patient has failed corticosteroid therapy within the last 30 days OR
 - 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR

Criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 1 month

Other Criteria:

- c. Patient has a diagnosis of rheumatic disorder (e.g., ankylosing spondylitis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, rheumatoid arthritis) AND ALL of the following:
 - i. The requested agent will be used as adjunct therapy for short-term administration (to tide the patient over an acute episode or exacerbation) AND
 - ii. There is evidence of a claim that the patient is currently being treated with a conventional agent within the past 90 days [e.g., DMARD (methotrexate, leflunomide), biologics (Humira)] to control disease progression AND

- iii. ONE of the following:
 - 1. Patient has failed corticosteroid therapy within the last 30 days OR
 - 2. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR
- d. Patient has a diagnosis of systemic lupus erythematosus (SLE) disease AND the patient will continue standard SLE therapy [corticosteroids (e.g., methylprednisolone, prednisone), hydroxychloroquine, immunosuppressives (e.g., azathioprine, methotrexate, oral cyclophosphamide)] in combination with the requested agent OR
- e. Patient has another FDA approved indication AND ONE of the following:
 - i. Patient has failed corticosteroid therapy within the last 30 days OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) OR
- f. Patient has another indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:
 - i. Patient has failed corticosteroid therapy within the last 30 days OR
 - ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to corticosteroid therapy (e.g., methylprednisolone) AND
- 2. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

Prior Authorization Group Description:

Cotempla PA

Drug Name(s)

Cotempla Xr-Odt

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:

Cresemba PA

Drug Name(s)

Cresemba

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of invasive aspergillosis OR
- B. Patient has a diagnosis of invasive mucormycosis OR
- C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:

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

2. ONE of the following

- A. Patient has a diagnosis of invasive aspergillosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
- B. Patient has a diagnosis of invasive mucormycosis and patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) OR
- C. BOTH of the following:
 - i. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
 - ii. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Crinone PA

Drug Name(s)

Crinone

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

Requested agent will be used to treat infertility AND FDA labeled contraindications to the requested agent

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:

Crysvita PA

Drug Name(s)

Crysvita

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. BOTH of the following:

i. Patient has a diagnosis of X-linked hypophosphatemia (XLH) as confirmed by ONE of the following:

- a. Genetic testing OR
- b. Elevated levels of intact fibroblast growth factor 23 (FGF23) OR
- c. Prescriber has provided information indicating the patient has a positive family history of XLH AND

ii. ONE of the following:

- a. Patient's epiphyseal plate has not fused OR
- b. Patient's epiphyseal plate has fused AND the patient is experiencing symptoms of XLH (e.g., bone pain, fractures, limited mobility) OR

B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND BOTH of the following:

- i. The requested agent is being used to treat FGF23 related hypophosphatemia AND
- ii. The tumor cannot be curatively surgically resected or localized AND

2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

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

2. ONE of the following:

A. Patient has a diagnosis of X-linked hypophosphatemia (XLH) OR

B. Patient has a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND

3. Patient has had clinical benefit with the requested agent (e.g., enhanced height velocity, improvement in lower extremity bowing and associated abnormalities, radiographic evidence of epiphyseal healing, improvement in bone pain, enhanced mobility, improvement in osteomalacia, improvement in fracture healing) AND

4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

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

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Cutaquig PA

Drug Name(s)

Cutaquig

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. 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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) 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

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:

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:

Cystinosis Agents PA – Procysbi

Drug Name(s)

Procysbi

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:

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:

Dalfampridine PA

Drug Name(s)

Ampyra

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:

Daybue PA

Drug Name(s)

Daybue

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require the following:

1. Patient has a diagnosis of Rett syndrome (RTT) with genetic analysis confirming mutation in the MECP2 gene

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 Rett syndrome (RTT) AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

Prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) 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:

Daytrana PA

Drug Name(s)

Daytrana

Methylphenidate Pad

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:

Dayvigo PA

Drug Name(s)

Dayvigo

Indications:

All FDA-Approved Indications.

Off-Label Uses:

Exclusion Criteria:

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

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

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Deferiprone PA

Drug Name(s)

Deferiprone

Ferriprox

Ferriprox Twice-A-Day

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 a diagnosis of transfusional iron overload due to thalassemia syndromes OR

B. Patient has a diagnosis of transfusional iron overload due to sickle cell disease or other anemias AND

2. Patient will NOT be using the requested agent in combination with another iron chelating agent (e.g., deferasirox) 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:

DHE 45 PA

Drug Name(s)

D.H.E. 45

Dihydroergotamine Mesylate (DHE 45)

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. The requested agent will be used for the treatment of acute migraine with or without aura
OR
- B. The requested agent will be used for the acute treatment of cluster headache episodes
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. ONE of the following:

- A. The requested agent will be used for the treatment of acute migraine with or without aura
OR
- B. The requested agent will be used for the acute treatment of cluster headache episodes
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:

Doptelet PA

Drug Name(s)

Doptelet

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has a diagnosis of thrombocytopenia AND ALL of the following:
 - A. Patient has chronic liver disease AND
 - B. Patient has a platelet count less than $50 \times 10^9/L$ AND
 - C. Patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) AND
 - D. The requested dose is within FDA labeled dosing for the requested indication AND
 - E. The length of therapy of the requested agent is within the FDA labeled duration for the requested indication OR
2. Patient has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
 - A. Patient has tried and had an insufficient response to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - B. Patient has an intolerance or hypersensitivity to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - C. Patient has an FDA labeled contraindication to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - D. Patient has had an insufficient response to a splenectomy

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Initial (I) 6 mo ITP, Renewal (R) 12 mo ITP. I & R 1 mo thrombocytopenia w/chronic liver disease

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 following:
 - A. Patient has a diagnosis of thrombocytopenia AND ALL of following:
 - i. Patient has chronic liver disease AND
 - ii. Patient has a platelet count less than $50 \times 10^9/L$ AND
 - iii. Patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) AND
 - iv. The requested dose is within FDA labeled dosing for the requested indication AND
 - v. The length of therapy of the requested agent is within the FDA labeled duration for the requested indication OR

B. Patient has a diagnosis of 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

Prior Authorization Group Description:

Droxidopa PA

Drug Name(s)

Droxidopa

Northera

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND
2. Prescriber has performed baseline blood pressure readings while the patient is sitting or supine (lying face up), AND also within three minutes of standing from a supine position AND
3. Patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing AND
4. Patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following:
 - A. Primary autonomic failure [Parkinson's disease (PD), multiple system atrophy, or pure autonomic failure] OR
 - B. Dopamine beta-hydroxylase deficiency OR
 - C. Non-diabetic autonomic neuropathy AND
5. Prescriber has assessed the severity of the patient's baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND
6. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND
3. Patient has had improvements or stabilization with the requested agent as indicated by improvement in severity from baseline symptoms of ONE of the following:
 - A. Dizziness
 - B. Lightheadedness
 - C. Feeling faint
 - D. Feeling like the patient may black out AND
4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Dupixent PA

Drug Name(s)

Dupixent

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of:

1. ONE of:

A. Patient (pt) has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of:

i. ONE of:

- a. Pt has tried and failed a topical steroid (e.g., triamcinolone) AND for pts 2 years of age or over, a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR
- b. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to a topical steroid AND for pts 2 years of age or over, a topical calcineurin inhibitor AND

ii. Pt will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR

B. Pt has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND ALL of:

i. Pt has ONE of:

- a. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months OR
- b. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR
- c. Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered OR
- d. Pt has a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted AND

ii. ONE of:

- a. Pt is NOT currently being treated with the requested agent AND is currently being treated with a maximally tolerated inhaled corticosteroid (ICS) OR
- b. Pt is currently being treated with the requested agent AND ONE of:
 - 1. Pt is currently being treated with an ICS that is adequately dosed to control symptoms OR
 - 2. Pt is currently being treated with a maximally tolerated ICS OR
 - 3. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to an ICS AND

iii. ONE of:

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

Initial criteria continues: see Other Criteria

Age Restriction:

For diagnosis of moderate-to-severe atopic dermatitis, patient is 6 months of age or over. For diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma, patient is 6 years of age or over. For diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), patient is 18 years of age or over. For diagnosis of eosinophilic esophagitis (EoE), patient is 12 years of age or over. For diagnosis of PN, patient is 18 years of age or over.

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- 2. A leukotriene receptor antagonist (LRTA) OR
 - 3. A long-acting muscarinic antagonist (LAMA) OR
 - 4. Theophylline OR
 - b. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to a LABA, LRTA, LAMA, or theophylline AND
 - iv. Pt will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND
 - v. Pt will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication OR
 - C. Pt has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND the following:
 - i. BOTH of:
 - a. ONE of:
 - 1. Pt has tried and had an inadequate response to an oral systemic corticosteroid AND an intranasal corticosteroid (e.g., fluticasone) OR
 - 2. Pt has an intolerance, hypersensitivity, or an FDA labeled contraindication to an oral systemic corticosteroid AND an intranasal corticosteroid AND
 - b. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR
 - D. Pt has a diagnosis of eosinophilic esophagitis (EoE) confirmed by esophageal biopsy OR
 - E. Pt has a diagnosis of prurigo nodularis (PN) AND
2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of:

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

2. ONE of:
- A. BOTH of:
 - i. Pt has a diagnosis of moderate-to-severe atopic dermatitis AND
 - ii. Pt will NOT be using the requested agent in combination with another biologic agent or a JAK inhibitor for the requested indication (e.g., Adbry, Cibinqo, Opzelura, Rinvoq) OR
 - B. Pt has a diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma AND ALL of:
 - i. ONE of:
 - a. Pt is currently being treated with standard therapy [e.g., ICS, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline] OR
 - b. Pt has an intolerance, hypersensitivity, or FDA labeled contraindication to a standard therapy AND
 - ii. Pt will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
 - iii. Pt will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenna, Nucala) for the requested indication OR
 - C. Pt has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND the following:
 - i. Pt will continue standard maintenance therapy (e.g., intranasal corticosteroid) in combination with the requested agent OR
 - D. Pt has a diagnosis of eosinophilic esophagitis (EoE) OR
 - E. Pt has a diagnosis of prurigo nodularis (PN) AND
3. Pt has had clinical benefit with the requested agent AND
4. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:

Elmiron PA

Drug Name(s)

Elmiron

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. The requested agent will be used for the relief of bladder pain or discomfort associated with interstitial cystitis AND
2. The requested dose is within the 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. The requested agent will be used for the relief of bladder pain or discomfort associated with interstitial cystitis AND
3. Patient has had clinical benefit with the requested agent (e.g., decreased bladder pain, decreased frequency or urgency of urination) AND
4. The requested dose is within the 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:

Emflaza PA

Drug Name(s)

Emflaza

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 Duchenne muscular dystrophy (DMD) confirmed by ONE of the following:
 - A. Presence of abnormal dystrophin OR
 - B. Confirmed mutation of the dystrophin gene 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 Duchenne muscular dystrophy (DMD) AND
3. Patient has had improvement, stabilization of the disease, or clinical benefit from baseline (e.g., improved strength and timed motor function, improved pulmonary function, reduced the need for scoliosis surgery) AND
4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

Patient is within the FDA labeled age for the requested agent

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:

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:

Endari PA

Drug Name(s)

Endari

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 sickle cell disease AND
2. Patient is using the requested agent to reduce the acute complications of sickle cell disease AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to maximally tolerated dose of hydroxyurea OR
 - B. Patient has an intolerance or hypersensitivity to hydroxyurea OR
 - C. Patient has an FDA labeled contraindication to hydroxyurea AND
4. The requested dose is within FDA labeled dosing for the requested indication

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:

Enspryng PA

Drug Name(s)

Enspryng

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 neuromyelitis optica spectrum disorder (NMOSD) AND
2. Patient is anti-aquaporin-4 (AQP4) antibody positive AND
3. Prescriber has screened the patient for hepatitis B viral (HBV) infection and determined to NOT have active hepatitis B viral infection AND
4. Patient does NOT have active or untreated tuberculosis AND
5. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND
3. Patient has had clinical benefit with the requested agent (e.g., decreased relapses, improvement or stabilization of vision or paralysis) AND
4. Patient does NOT have active hepatitis B virus (HBV) infection AND
5. Patient does NOT have active or untreated tuberculosis AND
6. 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., 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:

Epclusa PA

Drug Name(s)

Epclusa

Sofosbuvir/Velpatasvir

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. ONE of the following:

- A. Patient has a diagnosis of hepatitis C confirmed by serological markers OR
- B. Patient is a hepatitis C virus (HCV) - uninfected solid organ transplant recipient AND BOTH of the following:
 - i. Patient received an HCV - viremic donor organ AND
 - ii. The requested agent is being used for prophylaxis AND

2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND

3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND

4. The dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND

5. ONE of the following:

- A. The requested agent is the preferred agent: Epclusa OR
- B. The requested agent is the non-preferred agent: sofosbuvir/velpatasvir AND ONE of the following:
 - i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
 - ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
 - iii. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
 - iv. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Epidiolex PA

Drug Name(s)

Epidiolex

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of seizures associated with ONE of the following:

A. Lennox-Gastaut syndrome OR

B. Dravet syndrome OR

C. Tuberous sclerosis complex AND

2. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Erythropoietin Stimulating Agents PA – Aranesp

Drug Name(s)

Aranesp Albumin Free

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

A. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:

- i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND
- ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND
- iii. The intent of chemotherapy is non-curative OR

B. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:

- i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND
- ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
- iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR

C. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR

D. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

6 months for chemotherapy, 12 months for other indications

Other Criteria:

Prior Authorization Group Description:

Erythropoietin Stimulating Agents PA - Epogen/Procrit

Drug Name(s)

Epogen

Procrit

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR

B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND

iii. The intent of chemotherapy is non-curative OR

C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks) AND

ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND

iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR

D. Anemia due to myelodysplastic syndrome AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) OR

E. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks)

OR

Initial criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

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

Other Criteria:

F. Another indication that is supported in CMS approved compendia for the requested agent
AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR
less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4
weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

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

Prior Authorization Group Description:

Erythropoietin Stimulating Agents PA – Retacrit

Drug Name(s)

Retacrit

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require BOTH of the following:

1. The requested agent is being prescribed for ONE of the following:

A. To reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but 13 g/dL or less OR

B. Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR less than 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

ii. Patient is being concurrently treated with chemotherapy with or without radiation (treatment period extends to 8 weeks post chemotherapy) AND

iii. The intent of chemotherapy is non-curative OR

C. Anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:

i. Patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy OR 11 g/dL or less for patients stabilized on therapy (measured within the previous 4 weeks)

AND

ii. The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND

iii. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR

D. Anemia resulting from zidovudine treatment of HIV infection AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks)

OR

E. Another indication that is supported in CMS approved compendia for the requested agent AND the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy OR less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks) AND

2. Patient's transferrin saturation and serum ferritin have been evaluated

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

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Esbriet PA

Drug Name(s)

Esbriet

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:

Evenity PA

Drug Name(s)

Evenity

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 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 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

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

Criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

No prior use approve 12 months, Prior use approve remainder of 12 months of total cumulative therapy

Other Criteria:

2. ONE of the following:

- A. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
 - B. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
 - C. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) AND
3. Patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), or parathyroid hormone analog (e.g., abaloparatide, teriparatide) for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication AND
5. The total cumulative duration of treatment with Evenity (romosozumab-aqqg) has not exceeded 12 months

Prior Authorization Group Description:

Evkeeza PA

Drug Name(s)

Evkeeza

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 homozygous familial hypercholesterolemia (HoFH) AND
2. ONE of the following:
 - A. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene OR
 - B. 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
 - C. Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) AND
3. ONE of the following:
 - A. Patient is currently being treated with a lipid-lowering regimen in the past 90 days (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9) OR
 - B. Patient has an intolerance or hypersensitivity to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9) OR
 - C. Patient has an FDA labeled contraindication to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9) AND
4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

Patient is within FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
3. Patient has had clinical benefit with the requested agent AND
4. ONE of the following:
 - A. Patient is currently being treated with a lipid-lowering regimen in the past 90 days (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9) OR

B. Patient has an intolerance or hypersensitivity to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9)

OR

C. Patient has an FDA labeled contraindication to a lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe, atorvastatin in combination with ezetimibe, OR PCSK9)

AND

5. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:

Evrysdi PA

Drug Name(s)

Evrysdi

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require the following:

1. Patient has a diagnosis of Spinal Muscular Atrophy (SMA) as confirmed by genetic testing

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 Spinal Muscular Atrophy (SMA) AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Eysuvis PA

Drug Name(s)

Eysuvis

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 1 month

Other Criteria:

Prior Authorization Group Description:

Fasenra PA

Drug Name(s)

Fasenra

Fasenra Pen

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

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

Initial criteria continues: see Other Criteria

Age Restriction:

Patient is 12 years of age or over

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND
6. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND
7. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

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

AND

2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype

AND

3. Patient has had clinical benefit with the requested agent AND

4. ONE of the following:

A. Patient is currently being treated with standard therapy [e.g., ICS, LABA, LTRA, LAMA, theophylline] OR

B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy AND

5. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Nucala) for the requested indication AND

6. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND

7. The requested dose is within the FDA labeled dosing for the requested indication

Prior Authorization Group Description:

Fentanyl Nasal PA - Lazanda

Drug Name(s)

Lazanda

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 nasal 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 18 years of age or over

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Fentanyl Oral PA - Fentanyl lozenge

Drug Name(s)

Actiq

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:

Fentanyl Oral PA – Fentora

Drug Name(s)

Fentanyl Citrate

Fentora

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 18 years of age or over

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Fentanyl Oral PA – Subsys

Drug Name(s)

Subsys

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 18 years of age or over

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Filspari PA

Drug Name(s)

Filspari

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND
2. The requested agent will be used to reduce proteinuria AND
3. Patient is at risk of rapid disease progression as shown by ONE of the following:
 - A. A urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g OR
 - B. Proteinuria greater than or equal to 0.8 g/day AND
4. ONE of the following:
 - A. Patient has tried and had an inadequate response with a maximally tolerated ACE or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACE or ARB OR
 - B. Patient has an intolerance or hypersensitivity to an ACE or ARB, or a combination medication containing an ACE or ARB, that is not expected to occur with the requested agent OR
 - C. Patient has an FDA labeled contraindication to an ACE or ARB, or a combination medication containing an ACE or ARB, that is not expected to occur with 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 a diagnosis of primary immunoglobulin A nephropathy (IgAN) AND
3. The requested agent will be used to reduce proteinuria AND
4. 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., 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:

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:

Firdapse PA

Drug Name(s)

Firdapse

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. Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by at least ONE of the following:
 - A. Electrodiagnostic studies (e.g., electromyography) OR
 - B. Antibody testing

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 Lambert-Eaton myasthenic syndrome (LEMS) AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is 6 years of age or over

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:

Focalin PA

Drug Name(s)

Dexmethylphenidate Hydrochloride

Focalin

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:

Focalin XR PA

Drug Name(s)

Dexmethylphenidate Hydrochloride Er

Focalin Xr

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:

Galafold PA

Drug Name(s)

Galafold

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 Fabry disease AND
2. The diagnosis was confirmed by mutation of alpha-galactosidase A (alpha-gal A) gene AND
3. Patient has an amenable galactosidase alpha gene (GLA) variant mutation AND
4. Prescriber has evaluated at least ONE of the following: kidney function (e.g., proteinuria, GFR), cardiac function (e.g., left ventricular hypertrophy, conduction or rhythm, mitral or aortic insufficiency), optic neuropathy, neuropathic pain, and/or gastrointestinal symptoms

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 Fabry disease AND
3. Patient has had clinical benefit with the requested agent [e.g., improvement or stabilization of at least ONE of the following: kidney function (e.g., proteinuria, GFR), cardiac function (e.g., left ventricular hypertrophy, conduction or rhythm, mitral or aortic insufficiency), optic neuropathy, neuropathic pain, gastrointestinal symptoms]

Age Restriction:**Prescriber Restrictions:**

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

Gamastan PA

Drug Name(s)

Gamastan

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. 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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

C. Hepatitis A infection prophylaxis AND exposure occurred within the past 2 weeks OR

D. Measles (rubeola) prophylaxis AND BOTH of the following:

i. Patient is considered susceptible to infection (a susceptible person is defined as one who has not been vaccinated and has not had measles previously) AND

ii. Patient was exposed to measles (rubeola) within the past 6 days OR

E. Passive immunization against varicella AND BOTH of the following:

i. Patient is immunocompromised AND

ii. Varicella-Zoster immune globulin is unavailable OR

F. Rubella prophylaxis in exposed pregnant woman AND the patient is considered susceptible to infection (a susceptible person is defined as one who has not been vaccinated and has not had rubella previously) 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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

For prophylaxis diagnoses: see Other Criteria, for all other diagnoses 12 months

Other Criteria:

Prophylaxis indication with 3 months approval: Hepatitis A infection prophylaxis

Prophylaxis indications with 1 month approval: measles (rubeola) prophylaxis, passive immunization against varicella, rubella prophylaxis in exposed pregnant woman

Prior Authorization Group Description:

Gammagard/Gammaked/Gamunex-C PA

Drug Name(s)

Gammagard Liquid

Gammagard S/D IgA Less Than 1Mcg/ML

Gammaked

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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:

- i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

J. Refractory pemphigus vulgaris AND ONE of the following:

- i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR

2. ONE of the following:

- A. Patient has another FDA labeled indication for the requested agent OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

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

Prior Authorization Group Description:

Gattex PA

Drug Name(s)

Gattex

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of short bowel syndrome (SBS) AND
2. Patient is dependent on parenteral nutrition OR intravenous (PN/IV) fluids AND
3. ONE of the following:
 - A. Patient is aged 1 year to 17 years AND BOTH of the following:
 - i. A fecal occult blood test has been performed within 6 months prior to initiating treatment with the requested agent AND
 - ii. ONE of the following:
 - a. There was no unexplained blood in the stool OR
 - b. There was unexplained blood in the stool AND a colonoscopy or a sigmoidoscopy was performed OR
 - B. Patient is 18 years of age or over AND BOTH of the following:
 - i. Patient has had a colonoscopy within 6 months prior to initiating treatment with the requested agent AND
 - ii. If polyps were present at this colonoscopy, the polyps were removed AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of short bowel syndrome (SBS) AND
3. Patient has had a reduction from baseline in parenteral nutrition OR intravenous (PN/IV) fluids AND
4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Gaucher Enzyme Replacement PA – Cerezyme

Drug Name(s)

Cerezyme

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, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
 - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
 - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
 - C. Hepatomegaly OR
 - D. Splenomegaly OR
 - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
 - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
 - A. Hemoglobin (Hb) level OR
 - B. Platelet count OR
 - C. Liver volume OR
 - D. Spleen volume OR
 - E. Growth velocity OR
 - F. Bone pain or disease

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:

Gaucher Enzyme Replacement PA – Elelyso

Drug Name(s)

Elelyso

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, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
 - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
 - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
 - C. Hepatomegaly OR
 - D. Splenomegaly OR
 - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
 - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
 - A. Hemoglobin (Hb) level OR
 - B. Platelet count OR
 - C. Liver volume OR
 - D. Spleen volume OR
 - E. Growth velocity OR
 - F. Bone pain or disease

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:

Gaucher Enzyme Replacement PA – Vpriv

Drug Name(s)

Vpriv

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, platelet count, liver volume, and spleen volume AND
3. Prior to any treatment for the intended diagnosis, the patient has had at least ONE of the following clinical presentations:
 - A. Anemia [defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender] OR
 - B. Thrombocytopenia (defined as a platelet count of less than 100,000 per microliter) OR
 - C. Hepatomegaly OR
 - D. Splenomegaly OR
 - E. Growth failure (i.e., growth velocity below the standard mean for age) OR
 - F. Evidence of bone disease with other causes ruled out

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Gaucher disease type 1 (GD1) AND
3. Patient has had improvement and/or stabilization from baseline in at least ONE of the following:
 - A. Hemoglobin (Hb) level OR
 - B. Platelet count OR
 - C. Liver volume OR
 - D. Spleen volume OR
 - E. Growth velocity OR
 - F. Bone pain or disease

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:

Gralise PA

Drug Name(s)

Gralise

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 Postherpetic Neuralgia (PHN) AND
2. ONE of the following:
 - A. Patient has tried and had an inadequate response to immediate-release gabapentin OR
 - B. Patient has an intolerance or hypersensitivity to immediate-release gabapentin OR
 - C. Patient has an FDA labeled contraindication to immediate-release gabapentin that is not expected to occur with 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 a diagnosis of Postherpetic Neuralgia (PHN) AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Growth Hormone PA – Genotropin

Drug Name(s)

Genotropin

Genotropin Miniquick

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 BOTH of 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. 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 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 standard deviations (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 AND

2. ONE of the following:

- a. Patient has tried and failed the preferred agent [Omnitrope] OR
- b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

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 requested 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 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 BOTH of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of 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. Patient has a diagnosis of 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 GH stimulation test as an adult OR
 - c. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two growth hormone (GH) stimulation tests as an adult AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

Growth Hormone PA – Humatrope

Drug Name(s)

Humatrope

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 BOTH of the following:

1. ONE of the following:

- a. Patient has a diagnosis of Turner Syndrome* OR
 - b. Patient has a diagnosis of SHOX gene deficiency 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. ONE of the following:
 - a) Height more than 2 standard deviation (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 2 years AND
 - ii. Failure of at least 2 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* 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 AND
2. Patient's diagnosis is indicated in the preferred GH agent AND ONE of the following:
- a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

NOTE:

*Use of the preferred agent [Omnitrope] is required

NO prerequisites are required for the diagnosis of SHOX gene deficiency

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 requested 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. Small for Gestational Age OR
 - d. SHOX gene deficiency 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 BOTH of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of 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. Patient has a diagnosis of 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. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two GH stimulation tests as an adult AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

Growth Hormone PA – Norditropin

Drug Name(s)

Norditropin Flexpro

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 BOTH of 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 Noonan Syndrome OR
 - d. 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
 - e. Patient has a diagnosis of growth hormone deficiency (GHD)* or short stature* AND BOTH of the following:
 - i. 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 2 years AND
 - ii. Failure of at least 2 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
 - f. Patient has a diagnosis of small for gestational age* 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 AND
2. Patient's diagnosis is indicated in the preferred GH agent AND ONE of the following:
- a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

NOTE:

*Use of the preferred agent [Omnitrope] is required

NO prerequisites are required for the diagnosis of Noonan Syndrome

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 requested agent through the plan's Prior Authorization criteria AND
2. Patient has been diagnosed with ONE of the following:
 - a. Growth Hormone Deficiency (GHD), Short Stature OR
 - b. Noonan Syndrome OR
 - c. Panhypopituitarism OR
 - d. Small for Gestational Age OR
 - e. Turner Syndrome OR
 - f. Prader-Willi 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 BOTH of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of childhood 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. Patient has a diagnosis of 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. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two GH stimulation tests as an adult AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

Growth Hormone PA – Nutropin

Drug Name(s)

Nutropin Aq Nuspin 10

Nutropin Aq Nuspin 20

Nutropin Aq Nuspin 5

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 BOTH of the following:

1. ONE of the following:

- a. Patient has a diagnosis of Turner Syndrome* OR
- b. Patient has a diagnosis of chronic renal insufficiency AND BOTH of the following:
 - i. Height velocity (HV) is greater than or equal to 1.88 standard deviations (SD) below the mean or less than the third percentile for age and sex AND
 - ii. Other etiologies for growth impairment have been addressed 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 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. ONE of the following:
 - a) Height more than 2 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 2 years AND
 - ii. Failure of at least 2 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) AND

2. Patient's diagnosis is indicated in the preferred GH agent AND ONE of the following:

- a. Patient has tried and failed the preferred agent [Omnitrope] OR
- b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

NOTE:

*Use of the preferred agent [Omnitrope] is required

NO prerequisites are required for the diagnosis of chronic renal insufficiency

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 requested 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. Chronic renal insufficiency OR
 - c. Panhypopituitarism OR
 - d. 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 BOTH of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of 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. Patient has a diagnosis of 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. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two growth hormone (GH) stimulation tests as an adult AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

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:

Growth Hormone PA – Saizen

Drug Name(s)

Saizen

Saizenprep Reconstitution kit

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 BOTH of the following:

1. ONE of the following:
 - a. 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
 - b. Patient has a diagnosis of growth hormone deficiency (GHD) or short stature AND BOTH of the following:
 - i. 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 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) AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

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 requested 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 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 BOTH of the following:

1. ONE of the following:

- a. Patient has a diagnosis of 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. Patient has a diagnosis of 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. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two growth hormone (GH) stimulation tests as an adult AND

2. ONE of the following:

- a. Patient has tried and failed the preferred agent [Omnitrope] OR
- b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

Growth Hormone PA – Serostim

Drug Name(s)

Serostim

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. The requested agent is for the treatment of an HIV patient with wasting or cachexia AND
2. BOTH of the following:
 - a. The requested agent will be used in combination with antiretroviral therapy AND
 - b. ONE of the following:
 - i. Patient has had an unintentional weight loss of 10% or more of body weight over 12 months OR
 - ii. Patient has had an unintentional weight loss of greater than 7.5% over 6 months OR
 - iii. Patient has a mid-upper arm circumference less than 10th percentile OR
 - iv. Patient has a body cell mass (BCM) loss of 5% or more over 6 months OR
 - v. Patient's sex is male, has a BCM less than 35% AND a BMI of less than 27 kg/m² OR
 - vi. Patient's sex is female, has a BCM less than 23% AND a BMI of less than 27 kg/m²

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 is for the treatment of an HIV patient with wasting or cachexia AND
3. BOTH of the following:
 - a. The requested agent will be used in combination with antiretroviral therapy AND
 - b. Patient has had clinical benefit with the requested agent (e.g., weight increase or weight stabilization)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 weeks

Other Criteria:

Prior Authorization Group Description:

Growth Hormone PA – Skytrofa

Drug Name(s)

Skytrofa

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

For Children – Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of growth hormone deficiency (GHD), short stature, or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:
 - a. ONE of the following:
 - i. Height more than 2 standard deviations (SD) below the mean for age and sex OR
 - ii. Height more than 1.5 SD below the midparental height OR
 - iii. A decrease in height SD of more than 0.5 over one year in children at least 2 years of age OR
 - iv. Height velocity more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years AND
 - b. Failure of at least 2 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) AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Children – 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 growth hormone deficiency (GHD), short stature, or growth failure due to inadequate secretion of endogenous growth hormone 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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Growth Hormone PA – Zomacton

Drug Name(s)

Zomacton

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 BOTH of the following:

1. ONE of the following:

- a. Patient has a diagnosis of Turner Syndrome* OR
 - b. Patient has a diagnosis of SHOX gene deficiency 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. ONE of the following:
 - a) Height more than 2 standard deviation (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 2 years AND
 - ii. Failure of at least 2 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* 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 AND
2. Patient's diagnosis is indicated in the preferred GH agent AND ONE of the following:
- a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

NOTE:

*Use of the preferred agent [Omnitrope] is required

NO prerequisites are required for the diagnosis of SHOX gene deficiency

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 requested 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. Small for Gestational Age OR
 - d. SHOX gene deficiency 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 BOTH of the following:

1. ONE of the following:
 - a. Patient has a diagnosis of 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. Patient has a diagnosis of 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. Patient has a diagnosis of idiopathic GHD (adult or childhood onset) AND the patient has failed at least two GH stimulation tests as an adult AND
2. ONE of the following:
 - a. Patient has tried and failed the preferred agent [Omnitrope] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent [Omnitrope]

For Adults – 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 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:

Growth Hormone PA – Zorbtive

Drug Name(s)

Zorbtive

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 short bowel syndrome (SBS) AND
2. Patient is receiving specialized nutritional support

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 SBS AND
3. Patient has had clinical benefit with the requested agent (e.g., decrease in enteral or parenteral nutrition requirements)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 4 weeks

Other Criteria:

Prior Authorization Group Description:

HAE PA – Berinert

Drug Name(s)

Berinert

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Criteria for renewal approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

HAE PA – Cinryze

Drug Name(s)

Cinryze

Indications:

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

Off-Label Uses:

Acute HAE attacks

Exclusion Criteria:

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

2. Patient has a diagnosis of hereditary angioedema (HAE) AND ONE of the following:
 - a. The requested agent will be used to treat acute HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for treatment of acute HAE attacks OR
 - b. The requested agent will be used for prophylaxis against HAE attacks AND the patient will NOT be using the requested agent in combination with another HAE agent indicated for prophylaxis against HAE attacks AND
3. Patient has had a decrease in the frequency or severity of acute attacks or has had stabilization of disease from use of the requested agent

Prior Authorization Group Description:

HAE PA – Haegarda

Drug Name(s)

Haegarda

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

Prior Authorization Group Description:

HAE PA – Icatibant

Drug Name(s)

Firazyr

Icatibant Acetate

Sajazir

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Criteria for renewal approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:**

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

HAE PA – Kalbitor

Drug Name(s)

Kalbitor

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Criteria for renewal approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

HAE PA – Orladeyo

Drug Name(s)

Orladeyo

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

Prior Authorization Group Description:

HAE PA – Ruconest

Drug Name(s)

Ruconest

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Criteria for renewal approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

HAE PA – Takhzyro

Drug Name(s)

Takhzyro

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

Prior Authorization Group Description:

Harvoni PA

Drug Name(s)

Harvoni

Ledipasvir/Sofosbuvir

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA dosing for the requested indication AND
5. ONE of the following:
 - A. The requested agent is the preferred agent: Harvoni OR
 - B. The requested agent is the non-preferred agent: ledipasvir/sofosbuvir AND ONE of the following:
 - i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
 - ii. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
 - iii. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
 - iv. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Hetlioz Capsule PA

Drug Name(s)

Hetlioz

Tasimelteon

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:

Hetlioz LQ Suspension PA

Drug Name(s)

Hetlioz Lq

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 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

2. The requested agent is being used to treat nighttime sleep disturbances associated with SMS

Age Restriction:

Patient is 3 to 15 years of age

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)

Ascomp/Codeine

Bentyl

Benztropine Mesylate

Bonjesta

Butalbital/Acetaminophen/Caffeine/Codeine

Butalbital/Aspirin/Caffeine/Codeine

Carbinoxamine Maleate

Clemastine Fumarate

Cyproheptadine Hydrochloride

Diclegis

Dicyclomine Hydrochloride

Diphenoxylate Hydrochloride/Atropine Sulfate

Diphenoxylate/Atropine

Disopyramide Phosphate

Doxylamine Succinate/Pyridoxine Hydrochloride

Fioricet/Codeine

Hydroxyzine Hydrochloride

Hydroxyzine Pamoate

Lomotil

Norpace

Norpace Cr

Phenergan

Promethazine Hcl Plain

Promethazine Hydrochloride

Promethazine Vc

Promethazine/Phenylephrine

Promethegan

Propantheline Bromide

Ryclora

Ryvent

Scopolamine

Transderm-Scop

Trihexyphenidyl Hydrochloride

Vistaril

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:

HoFH PA – Juxtapid

Drug Name(s)

Juxtapid

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 homozygous familial hypercholesterolemia (HoFH) AND
2. ONE of the following:
 - A. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene OR
 - B. 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
 - C. Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) AND
3. ONE of the following:
 - A. Patient is currently being treated with a maximally tolerated statin-containing lipid-lowering regimen in the last 90 days (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
 - B. Patient has an intolerance or hypersensitivity to a maximally tolerated statin-containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR
 - C. Patient has an FDA labeled contraindication to a maximally tolerated statin-containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe)

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
3. Patient has had clinical benefit with the requested agent AND
4. ONE of the following:
 - A. Patient is currently being treated with a maximally tolerated statin-containing lipid-lowering regimen in the last 90 days (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR

B. Patient has an intolerance or hypersensitivity to a maximally tolerated statin-containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR

C. Patient has an FDA labeled contraindication to a maximally tolerated statin-containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe)

Prior Authorization Group Description:

Horizant PA

Drug Name(s)

Horizant

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 Postherpetic Neuralgia (PHN) AND
 - ii. ONE of the following:
 1. Patient has tried and had an inadequate response to immediate-release gabapentin OR
 2. Patient has an intolerance or hypersensitivity to immediate-release gabapentin OR
 3. Patient has an FDA labeled contraindication to immediate-release gabapentin that is not expected to occur with the requested agent OR
 - B. BOTH of the following:
 - i. Patient has a diagnosis of moderate-to-severe primary Restless Legs Syndrome (RLS) AND
 - ii. BOTH of the following:
 1. ONE of the following:
 - a. Patient has tried and had an inadequate response to immediate-release ropinirole OR
 - b. Patient has an intolerance or hypersensitivity to immediate-release ropinirole OR
 - c. Patient has an FDA labeled contraindication to immediate-release ropinirole AND
 2. ONE of the following:
 - a. Patient has tried and had an inadequate response to immediate-release pramipexole OR
 - b. Patient has an intolerance or hypersensitivity to immediate-release pramipexole OR
 - c. Patient has an FDA labeled contraindication to immediate-release pramipexole

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 Postherpetic Neuralgia (PHN) OR

B. Patient has a diagnosis of moderate-to-severe primary Restless Legs Syndrome (RLS)
AND

3. Patient has had clinical benefit with the requested agent

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Hyftor PA

Drug Name(s)

Hyftor

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 facial angiofibroma associated with tuberous sclerosis 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:

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

Coverage Duration:

Approval will be for 12 weeks

Other Criteria:

Prior Authorization Group Description:

Ilaris PA

Drug Name(s)

Ilaris

Indications:

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

Off-Label Uses:

Acute gouty arthritis

Exclusion Criteria:**Required Medical Information:**

Criteria for approval require BOTH of:

1. ONE of the following:

- A. Patient (pt) has been diagnosed with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) OR
- B. Pt has been diagnosed with Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) OR
- C. Pt has been diagnosed with Familial Mediterranean Fever (FMF) AND ONE of the following:
 - i. Pt has tried and had an inadequate response to colchicine OR
 - ii. Pt has an intolerance or hypersensitivity to colchicine OR
 - iii. Pt has an FDA labeled contraindication to colchicine OR
- D. Pt has been diagnosed with Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) OR
- E. Pt has been diagnosed with active Systemic Juvenile Idiopathic Arthritis (SJIA) AND BOTH of the following:
 - i. Pt has documented active systemic features (e.g., ongoing fever, evanescent erythematous rash, generalized lymphadenopathy, 1 or more joints with active arthritis, hepatomegaly, splenomegaly, serositis) AND
 - ii. ONE of the following:
 - a. Pt has tried and had an inadequate response to at least ONE prerequisite agent (e.g., glucocorticosteroids, prescription oral NSAIDs, methotrexate, leflunomide, Humira) OR
 - b. Pt has an intolerance or hypersensitivity to at least ONE prerequisite agent OR
 - c. Pt has an FDA labeled contraindication to at least ONE prerequisite agent OR
- F. Pt has a diagnosis of adult onset Still's disease OR
- G. Pt has been diagnosed with acute gouty arthritis AND ONE of the following:
 - i. Pt has tried and had an inadequate response to at least TWO conventional first-line agents (e.g., prescription oral NSAIDs, colchicine, systemic corticosteroids) OR
 - ii. Pt has an intolerance or hypersensitivity to at least TWO conventional first-line agents OR
 - iii. Pt has an FDA labeled contraindication to at least TWO conventional first-line agents AND

2. Pt 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 4 years of age or over

For diagnosis of SJIA, patient is 2 years of age or over

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:

Inbrija PA

Drug Name(s)

Inbrija

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Ingrezza PA

Drug Name(s)

Ingrezza

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 tardive dyskinesia AND
2. ONE of the following:
 - A. Prescriber has reduced the dose of or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) OR
 - B. Prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Injectable Oncology PA

Drug Name(s)

Abraxane
Adcetris
Alimta
Aliqopa
Alymsys
Arranon
Arzerra
Avastin
Beleodaq
Besponsa
Blenrep
Blincyto
Bortezomib
Cycramza
Danyelza
Darzalex
Darzalex Faspro
Doxil
Doxorubicin Hydrochloride Liposome
Empliciti
Enhertu
Erbix
Faslodex
Folotyn
Fulvestrant
Gazyva
Halaven
Herceptin
Herceptin Hylecta
Herzuma
Infugem
Istodax (Overfill)
Jevtana
Kadcyla

Kanjinti
Kyprolis
Lumoxiti
Margenza
Monjuvi
Mvasi
Mylotarg
Nelarabine
Ogivri
Onivyde
Ontruzant
Padcev
Pemetrexed
Perjeta
Phesgo
Polivy
Portrazza
Poteligeo
Romidepsin
Rybrevant
Sarclisa
Synribo
Trazimera
Trodelvy
Unituxin
Vectibix
Velcade
Vegzelma
Vyxeos
Yondelis
Zaltrap
Zepzelca
Zirabev
Zynlonta

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:

Intrarosa PA

Drug Name(s)

Intrarosa

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:

Iron Chelating Agents PA – Exjade

Drug Name(s)

Deferasirox (Exjade)

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)

Jadenu

Jadenu Sprinkle

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:

Isturisa PA

Drug Name(s)

Isturisa

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 Cushing's disease AND
2. ONE of the following:
 - A. Patient had an inadequate response to pituitary surgical resection OR
 - B. Patient is NOT a candidate for pituitary surgical resection AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to pasireotide OR
 - B. Patient has an intolerance or hypersensitivity to pasireotide OR
 - C. Patient has an FDA labeled contraindication to pasireotide

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of Cushing's disease AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Ivermectin Cream PA

Drug Name(s)

Ivermectin Cream

Soolantra

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 Lotion PA

Drug Name(s)

Ivermectin Lotion

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

Stromectol

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:

Jatenzo PA

Drug Name(s)

Jatenzo

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's sex is male with a diagnosis of primary or secondary (hypogonadotropic) hypogonadism AND
2. 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 for 12 months

Other Criteria:

Prior Authorization Group Description:

Jornay PM PA

Drug Name(s)

Jornay Pm

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:

Jynarque PA

Drug Name(s)

Jynarque

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 autosomal dominant polycystic kidney disease confirmed by ONE of the following:
 - A. Ultrasound OR
 - B. MRI or CT scan OR
 - C. Genetic testing AND
2. Patient is at risk of rapid disease progression AND
3. ONE of the following:
 - A. Patient is initiating therapy with the requested agent AND BOTH of the following:
 - i. Patient's ALT, AST, and bilirubin have been measured AND
 - ii. The ALT, AST, and bilirubin levels are less than or equal to the upper limit of normal (ULN) OR
 - B. BOTH of the following:
 - i. Patient is continuing therapy with the requested agent AND
 - ii. Patient will continue to receive routine ALT, AST, and bilirubin monitoring at least every 3 months 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 autosomal dominant polycystic kidney disease AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will continue to receive routine ALT, AST, and bilirubin monitoring at least every 3 months 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., 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:

Kalydeco PA

Drug Name(s)

Kalydeco

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cystic fibrosis AND
2. ONE of the following:
 - A. Patient has ONE of the CFTR gene mutations or a mutation in the CFTR gene that is responsive based on in vitro data, as indicated in the FDA label, confirmed by genetic testing OR
 - B. Patient has another CFTR gene mutation(s) that is responsive to the requested agent, as indicated in the FDA label, confirmed by genetic testing AND
3. Patient is NOT homozygous for the F508del mutation AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cystic fibrosis AND
3. Patient has had improvement or stabilization with the requested agent [e.g., improvement in FEV1 from baseline, increase in weight/BMI, improvement from baseline Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] AND
4. Patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Kerendia PA

Drug Name(s)

Kerendia

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Keveyis PA

Drug Name(s)

Dichlorphenamide

Keveyis

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or a related variant

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:

Kynmobi PA

Drug Name(s)

Kynmobi

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 “off” episodes associated with 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:

Leuprolide PA

Drug Name(s)

Eligard

Fensolvi

Leuprolide Acetate

Lupaneta Pack

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 Gel/Jelly

Drug Name(s)

Glydo

Lidocaine Hcl Jelly

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. Surface anesthesia and lubrication for urethral procedure OR
 - B. Topical treatment for pain of urethritis OR
 - C. Surface anesthesia and lubrication for endotracheal intubation (oral and nasal) OR
 - D. 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 Ointment

Drug Name(s)

Lidocaine Ointment

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used for ONE of the following:

- A. Anesthesia of accessible mucous membranes of the oropharynx OR
- B. Anesthetic lubricant for intubation OR
- C. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites OR
- D. Another indication that is supported in CMS approved compendia for the requested agent

AND ONE of the following:

- i. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR
- ii. Patient has an intolerance or hypersensitivity to a conventional therapy OR
- iii. Patient has an FDA labeled contraindication to a conventional therapy

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Lidocaine Topical PA - Lidocaine Patch

Drug Name(s)

Lidocaine Patch

Lidoderm

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. Patient has ONE of the following diagnoses:

- A. Pain associated with postherpetic neuralgia (PHN) OR
 - B. Pain associated with diabetic neuropathy OR
 - C. Neuropathic pain associated with cancer, or cancer treatment OR
 - D. Another diagnosis that is supported in CMS approved compendia for the requested agent
- AND

2. ONE of the following:

- A. Patient has tried and had an inadequate response to a conventional therapy [e.g., gabapentin, pregabalin, oral prescription NSAID (non-steroidal anti-inflammatory drug)] for the requested indication OR
- B. Patient has an intolerance or hypersensitivity to a conventional therapy OR
- C. Patient has an FDA labeled contraindication to a conventional therapy

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Lidocaine Topical PA - Lidocaine Solution

Drug Name(s)

Lidocaine Solution

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

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:

Lidocaine Topical PA – Pliaglis

Drug Name(s)

Pliaglis

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. The requested agent will be used on intact skin of an adult patient to provide local analgesia for a superficial dermatological procedure (e.g., dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, laser-assisted tattoo removal)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Lidocaine Topical PA – ZTlido

Drug Name(s)

Ztlido

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Linezolid PA

Drug Name(s)

Linezolid

Zyvox

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:

Livmarli PA

Drug Name(s)

Livmarli

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 Alagille Syndrome (ALGS) AND
2. The requested agent will be used to treat cholestatic pruritus AND
3. 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:

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

Lupkynis PA

Drug Name(s)

Lupkynis

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 active lupus nephritis (LN) AND the following:
 - a. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
2. Patient will NOT be using the requested agent in combination with cyclophosphamide

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 active lupus nephritis (LN) AND the following:
 - a. Patient will continue standard LN therapy [corticosteroids (e.g., methylprednisolone, prednisone), immunosuppressives (e.g., azathioprine, mycophenolate)] in combination with the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with cyclophosphamide

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:

Mavyret PA

Drug Name(s)

Mavyret

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. ONE of the following:

- A. Patient has a diagnosis of hepatitis C confirmed by serological markers OR
- B. Patient is a hepatitis C virus (HCV) - uninfected solid organ transplant recipient AND BOTH of the following:
 - i. Patient received an HCV - viremic donor organ AND
 - ii. The requested agent is being used for prophylaxis AND

2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND

3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND

4. The dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND

5. ONE of the following:

- A. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
- B. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
- C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
- D. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Memantine ER PA

Drug Name(s)

Memantine Hydrochloride Er

Namenda Xr

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:

Memantine PA

Drug Name(s)

Memantine Hcl Titration Pak

Memantine Hydrochloride

Namenda

Namenda Titration Pak

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:

Methamphetamine PA

Drug Name(s)

Desoxyn

Methamphetamine Hcl

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

Requested agent will be used to promote weight loss AND 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:

Methylin PA

Drug Name(s)

Methylin

Methylphenidate Hydrochloride (Methylin)

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

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:

Methylphenidate Capsule PA

Drug Name(s)

Methylphenidate Hydrochloride Capsule

Methylphenidate Hydrochloride Er Capsule

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:

Methylphenidate Chewable PA

Drug Name(s)

Methylphenidate Hydrochloride Chewable

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:

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:

Methylphenidate LA Capsule PA

Drug Name(s)

Methylphenidate Hydrochloride La Capsule

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)

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

Provigil

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:

MS PA – Aubagio

Drug Name(s)

Aubagio

Teriflunomide

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 – Avonex

Drug Name(s)

Avonex

Avonex Pen

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Bafiertam

Drug Name(s)

Bafiertam

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Betaseron

Drug Name(s)

Betaseron

Extavia

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

Tecfidera

Tecfidera Starter Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Gilenya

Drug Name(s)

Fingolimod

Gilenya

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication AND
3. Prescriber has performed an electrocardiogram within 6 months prior to initiating treatment

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Glatiramer

Drug Name(s)

Copaxone

Glatiramer Acetate

Glatopa

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Kesimpta

Drug Name(s)

Kesimpta

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 – Mavenclad

Drug Name(s)

Mavenclad

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 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) 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 Mavenclad (cladribine) has not exceeded 4 treatment cycles

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

No prior use approve 2 years, Prior use approve remainder of 2 years of total cumulative therapy

Other Criteria:

Prior Authorization Group Description:

MS PA – Mayzent

Drug Name(s)

Mayzent

Mayzent Starter Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Plegridy

Drug Name(s)

Plegridy

Plegridy Starter Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Ponvory

Drug Name(s)

Ponvory

Ponvory 14-Day Starter Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Rebif

Drug Name(s)

Rebif

Rebif Rebidose

Rebif Rebidose Titration Pack

Rebif Titration Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Tascenso

Drug Name(s)

Tascenso

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication AND
3. Prescriber has performed an electrocardiogram within 6 months prior to initiating treatment

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Tysabri

Drug Name(s)

Tysabri

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 has been treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient has been treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
 - C. Patient has ONE of the following diagnoses:
 - i. Relapsing form of Multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease AND ONE of the following:
 - a. Prescriber states the patient has highly active disease OR
 - b. ONE of the following:
 1. Patient has tried and had an inadequate response to TWO preferred agents (Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR
 2. Patient has an intolerance or hypersensitivity to TWO preferred agents (Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR
 3. Patient has an FDA labeled contraindication to TWO preferred agents (Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

Initial criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months for MS, for CD 16 weeks for initial and 12 months renewal

Other Criteria:

- ii. Moderately to severely active Crohn's disease (CD) AND BOTH of the following:
 - a. ONE of the following:

1. Patient has tried and had an inadequate response to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) OR
 2. Patient has an intolerance or hypersensitivity to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) OR
 3. Patient has an FDA labeled contraindication to ONE conventional CD therapy (e.g., 6-mercaptopurine, azathioprine, corticosteroids, methotrexate) AND
- b. ONE of the following:
1. Patient has tried and had an inadequate response to ONE preferred biologic agent (Humira or Stelara) for the treatment of CD OR
 2. Patient has an intolerance or hypersensitivity to ONE preferred biologic agent (Humira or Stelara) OR
 3. Patient has an FDA labeled contraindication to ONE preferred biologic agent (Humira or Stelara) AND
 3. 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

Prior Authorization Group Description:

MS PA – Vumerity

Drug Name(s)

Vumerity

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require BOTH of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent AND
4. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

MS PA – Zeposia

Drug Name(s)

Zeposia

Zeposia 7-Day Starter Pack

Zeposia Starter Kit

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has an FDA labeled indication for the requested agent AND
2. Patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) or a biologic immunomodulator for the requested indication AND
3. ONE of the following:
 - i. The requested diagnosis is NOT moderately to severely active ulcerative colitis (UC) OR
 - ii. The requested diagnosis is moderately to severely active UC AND ONE of the following:
 1. Patient has tried and had an inadequate response to at least ONE conventional agent (e.g., 5-aminosalicylates [including balsalazide, mesalamine, olsalazine, sulfasalazine], mercaptopurine, azathioprine, corticosteroids [including budesonide EC capsule]) used in the treatment of UC OR
 2. Patient has severely active UC OR
 3. Patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC OR
 4. Patient has an FDA labeled contraindication to at least ONE of the conventional agents used in the treatment of UC OR
 5. Patient's medication history indicates use of a biologic immunomodulator agent that is FDA labeled for the treatment of UC

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:

Mulpleta PA

Drug Name(s)

Mulpleta

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 thrombocytopenia AND
2. Patient has chronic liver disease AND
3. Patient has a platelet count less than $50 \times 10^9/L$ AND
4. Patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) AND
5. The requested dose is within FDA labeled dosing for the requested indication AND
6. The length of therapy of the requested agent is within the FDA labeled duration for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 1 month

Other Criteria:

Prior Authorization Group Description:

Myalept PA

Drug Name(s)

Myalept

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

1. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
2. Prescriber has provided the patient's baseline levels for HbA1C, triglycerides, and fasting insulin, measured prior to beginning therapy with the requested agent AND
3. Patient also has at least ONE of the complications related to lipodystrophy: diabetes mellitus, hypertriglyceridemia (200 mg/dL or higher), and/or high fasting insulin (30µU/mL or higher) AND
4. Patient has tried and had an inadequate response to maximum tolerable dosing of a conventional agent for the additional diagnosis AND
5. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has leptin deficiency associated with a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND
3. Patient has had improvement or stabilization with the requested agent as indicated by change from baseline level of at least ONE of the following:
 - A. HbA1C
 - B. Triglycerides
 - C. Fasting insulin AND
4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Conventional agent examples include:

Hypertriglyceridemia: statins, fenofibrates, Omega-3-Acid Ethyl Esters (generic Lovaza)

Diabetes/high fasting insulin: insulin, sulfonylurea/sulfonylurea combination, metformin/metformin combination

Prior Authorization Group Description:

Myfembree PA

Drug Name(s)

Myfembree

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. BOTH of the following:
 - i. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND
 - ii. Patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) OR
 - B. Patient has a diagnosis of moderate to severe pain associated with endometriosis AND
2. Patient is premenopausal AND
3. Patient will NOT be using the requested agent in combination with another GnRH antagonist agent [e.g., Orilissa (elagolix), Oriahnn (elagolix, estradiol, norethindrone acetate)] for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication AND
5. ONE of the following:
 - A. Patient is initiating therapy with the requested agent OR
 - B. BOTH of the following:
 - i. Patient is continuing therapy with the requested agent and the prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent AND
 - ii. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

For no prior Myfembree use:

24 months

For prior Myfembree use:

Remainder of 24 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:

Nexletol PA

Drug Name(s)

Nexletol

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 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
- B. A diagnosis of established atherosclerotic cardiovascular disease (ASCVD) defined as having ONE of the following:
 - i. Acute coronary syndrome
 - ii. History of myocardial infarction
 - iii. Stable or unstable angina
 - iv. Coronary or other arterial revascularization
 - v. Stroke
 - vi. Transient ischemic attack
 - vii. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin AND

2. ONE of the following:

- A. Patient is on maximally tolerated statin therapy 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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has ONE of the following:
 - A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR
 - B. A diagnosis of established atherosclerotic cardiovascular disease (ASCVD) AND
3. ONE of the following:
 - A. Patient is on maximally tolerated statin therapy 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 has had clinical benefit with the requested agent

Prior Authorization Group Description:

Nexlizet PA

Drug Name(s)

Nexlizet

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 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
- B. A diagnosis of established atherosclerotic cardiovascular disease (ASCVD) defined as having ONE of the following:
 - i. Acute coronary syndrome
 - ii. History of myocardial infarction
 - iii. Stable or unstable angina
 - iv. Coronary or other arterial revascularization
 - v. Stroke
 - vi. Transient ischemic attack
 - vii. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin AND

2. ONE of the following:

- A. Patient is on maximally tolerated statin therapy 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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has ONE of the following:
 - A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR
 - B. A diagnosis of established atherosclerotic cardiovascular disease (ASCVD) AND
3. ONE of the following:
 - A. Patient is on maximally tolerated statin therapy 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 has had clinical benefit with the requested agent

Prior Authorization Group Description:

Nocdurna PA

Drug Name(s)

Nocdurna

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 nocturia due to nocturnal polyuria (awakening at least two times per night to void) AND
2. Diagnosis was confirmed by a nighttime urine production greater than one third of 24-hour urine collection AND
3. Patient's serum sodium concentration is within normal range [between 135 to 145 mEq/L (mmol/L) or within testing laboratory's normal range]

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 nocturia due to nocturnal polyuria (awakening at least two times per night to void) AND
3. Patient's serum sodium concentration is within normal range [between 135 to 145 mEq/L (mmol/L) or within testing laboratory's normal range] AND
4. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Nourianz PA

Drug Name(s)

Nourianz

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. The requested agent will be used as adjunctive treatment in patients with Parkinson's disease experiencing "off" episodes AND
2. The requested agent will be used in combination with levodopa/carbidopa agents

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:

Nucala PA

Drug Name(s)

Nucala

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 severe asthma with an eosinophilic phenotype AND ALL of the following:

i. 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

ii. ONE of the following:

- a. Patient is NOT currently being treated with the requested agent AND is currently being treated with a maximally tolerated inhaled corticosteroid (ICS) OR
- b. Patient is currently being treated with the requested agent AND ONE of the following:
 - 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

iii. 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 (LRTA) 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, LRTA, LAMA, or theophylline AND

- iv. Patient will continue asthma control therapy (e.g., ICS, LABA, LRTA, LAMA, theophylline) in combination with the requested agent OR

Initial criteria continues: see Other Criteria

Age Restriction:

Other Criteria:

- B. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the following:
 - i. ONE of the following:
 - a. Patient is currently being treated with a maximally tolerated oral corticosteroid OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an oral corticosteroid OR
 - C. Patient has a diagnosis of hypereosinophilic syndrome (HES) for 6 months or more without an identifiable non-hematologic secondary cause AND the following:
 - i. ONE of the following:
 - a. Patient is currently being treated with a maximally tolerated oral corticosteroid OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an oral corticosteroid OR
 - D. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND
- 2. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenna) 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 severe asthma with an eosinophilic phenotype AND BOTH of the following:
 - i. ONE of the following:
 - a. Patient is currently being treated with standard therapy [e.g., ICS, LABA, LRTA, LAMA, theophylline] OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy AND
 - ii. Patient will continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested agent OR
 - B. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the following:
 - i. ONE of the following:

- a. Patient is currently being treated with maintenance therapy with oral corticosteroid
 - OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroid OR
- C. Patient has a diagnosis of hypereosinophilic syndrome (HES) for 6 months or more without an identifiable non-hematologic secondary cause AND the following:
 - i. ONE of the following:
 - a. Patient is currently being treated with maintenance therapy with oral corticosteroid
 - OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroid OR
 - D. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND
- 3. Patient has had clinical benefit with the requested agent AND
- 4. Patient will NOT be using the requested agent in combination with Xolair, Dupixent, or with another injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra) for the requested indication AND
- 5. The requested dose is within FDA labeled dosing for the requested indication

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:

Ocaliva PA

Drug Name(s)

Ocaliva

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of primary biliary cholangitis (PBC) AND
3. ONE of the following:
 - A. Patient does NOT have cirrhosis OR
 - B. Patient has compensated cirrhosis with NO evidence of portal hypertension AND
4. ONE of the following:
 - A. The requested agent will be used in combination with ursodiol OR
 - B. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodiol AND

5. Patient has had improvements or stabilization with the requested agent as indicated by BOTH of the following:

- A. Decrease in alkaline phosphatase (ALP) level from baseline AND
- B. Total bilirubin is less than or equal to the upper limit of normal (ULN)

Prior Authorization Group Description:

Ofev PA

Drug Name(s)

Ofev

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require the following:

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:

Oncology Immunotherapy PA – Bavencio

Drug Name(s)

Bavencio

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Imfinzi

Drug Name(s)

Imfinzi

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Jemperli

Drug Name(s)

Jemperli

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Keytruda

Drug Name(s)

Keytruda

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Libtayo

Drug Name(s)

Libtayo

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Opdivo

Drug Name(s)

Opdivo

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Tecentriq

Drug Name(s)

Tecentriq

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oncology Immunotherapy PA – Yervoy

Drug Name(s)

Yervoy

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

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

2. ONE of the following:

A. There is evidence of a claim that the patient has been treated with the requested agent within the past 180 days OR

B. Prescriber states the patient has been treated with the requested agent OR

C. ALL of the following:

i. Genetic testing has been completed, if required, for therapy with the requested agent and results indicate the requested agent is appropriate AND

ii. ONE of the following:

a. Patient has tried appropriate FDA labeled or compendia supported therapy that are indicated in NCCN as first-line therapy OR

b. Patient has an intolerance or hypersensitivity to the first-line therapy for the requested indication OR

c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication AND

iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Ophthalmic Immunomodulators PA – Cequa

Drug Name(s)

Cequa

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. 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:

Ophthalmic Immunomodulators PA – Verkazia

Drug Name(s)

Verkazia

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. 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:

Ophthalmic Immunomodulators PA – Xiidra

Drug Name(s)

Xiidra

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:

Opioids ER PA - Buprenorphine Pain

Drug Name(s)

Belbuca

Buprenorphine

Butrans

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 - Fentanyl Patch

Drug Name(s)

Fentanyl

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR

B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:

i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR

ii. Prescriber states the patient has been treated with the requested agent within the past 90 days

OR

iii. ALL of the following:

a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:

1. Diagnosis AND

2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND

b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND

c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient

AND

d. ONE of the following:

1. Patient's medication history includes use of an immediate-acting opioid OR

2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR

3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND

e. Prescriber has confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND

f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Opioids ER PA – Hydrocodone

Drug Name(s)

Hydrocodone Bitartrate Er

Hysingla 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 – Hydromorphone

Drug Name(s)

Hydromorphone Hydrochloride Er

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require the following:

1. ONE of the following:

A. Patient has a diagnosis of chronic cancer pain due to an active malignancy OR

B. Patient is undergoing treatment of chronic non-cancer pain AND ONE of the following:

i. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR

ii. Prescriber states the patient has been treated with the requested agent within the past 90 days

OR

iii. ALL of the following:

a. Prescriber has provided documentation of a formal, consultative evaluation including BOTH of the following:

1. Diagnosis AND

2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND

b. The requested agent is NOT prescribed as an as-needed (prn) analgesic AND
c. Prescriber has confirmed that a patient-specific pain management plan is on file for the patient

AND

d. ONE of the following:

1. Patient's medication history includes use of an immediate-acting opioid OR

2. Patient has an intolerance or hypersensitivity to an immediate-acting opioid OR

3. Patient has an FDA labeled contraindication to an immediate-acting opioid AND

e. Prescriber has confirmed that the patient is not diverting controlled substances, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable AND

f. Patient does NOT have any FDA labeled contraindications to the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Opioids ER PA – Morphine

Drug Name(s)

Kadian

Morphine Sulfate Er

Ms Contin

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 – Oxycodone

Drug Name(s)

Oxycodone Hcl Er

Oxycontin

Xtampza 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 – Oxymorphone

Drug Name(s)

Oxymorphone Hydrochloride 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 – Tapentadol

Drug Name(s)

Nucynta 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)

Conzip

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:

Opzelura PA

Drug Name(s)

Opzelura

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

1. ONE of the following:

A. Patient has a diagnosis of mild to moderate atopic dermatitis AND ALL of the following:

i. The requested agent will be used for short-term and non-continuous chronic treatment AND

ii. Patient is NOT immunocompromised AND

iii. ONE of the following:

a. Patient has tried and failed a topical steroid (e.g., triamcinolone) OR

b. Patient has an intolerance or hypersensitivity to a topical steroid OR

c. Patient has an FDA labeled contraindication to a topical steroid AND

iv. ONE of the following:

a. Patient has tried and failed a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR

b. Patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor OR

c. Patient has an FDA labeled contraindication to a topical calcineurin inhibitor OR

B. Patient has a diagnosis of nonsegmental vitiligo AND

2. Patient will NOT be using the requested agent in combination with other biologic immunomodulator agents, other JAK inhibitors, OR potent immunosuppressants (e.g., azathioprine, cyclosporine) AND

3. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:

For diagnosis of mild to moderate atopic dermatitis, patient is 12 years of age or over. For diagnosis of nonsegmental vitiligo, patient is 12 years of age or over.

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 3 months for atopic dermatitis. 6 months for nonsegmental vitiligo.

Other Criteria:

Prior Authorization Group Description:

Oral Immunotherapy Agents PA – Grastek

Drug Name(s)

Grastek

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 allergic rhinitis, with or without conjunctivitis AND
2. Patient's diagnosis is confirmed with ONE of the following:
 - A. Positive skin test to ONE of the pollen extracts included in the requested agent OR
 - B. IgE specific antibodies to ONE of the extracts included in the requested agent: Timothy grass or cross-reactive grass AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - B. Patient has an intolerance or hypersensitivity to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - C. Patient has an FDA labeled contraindication to TWO standard allergy medications, one of which was an intranasal corticosteroid AND
4. Patient will NOT be using the requested agent in combination with a subcutaneous injectable immunotherapy agent AND
5. The requested agent will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season AND
6. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
7. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Standard allergy medications:

Oral antihistamines, oral corticosteroids, intranasal corticosteroids, intranasal antihistamines, or leukotriene inhibitors

Prior Authorization Group Description:

Oral Immunotherapy Agents PA – Odactra

Drug Name(s)

Odactra

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 allergic rhinitis, with or without conjunctivitis AND
2. Patient's diagnosis is confirmed with ONE of the following:
 - A. Positive skin test to licensed house dust mite allergen extracts OR
 - B. IgE specific antibodies to ONE of the extracts included in the requested agent: Dermatophagoides farinae or Dermatophagoides pteronyssinus AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - B. Patient has an intolerance or hypersensitivity to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - C. Patient has an FDA labeled contraindication to TWO standard allergy medications, one of which was an intranasal corticosteroid AND
4. Patient will NOT be using the requested agent in combination with a subcutaneous injectable immunotherapy agent AND
5. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
6. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Standard allergy medications:

Oral antihistamines, oral corticosteroids, intranasal corticosteroids, intranasal antihistamines, or leukotriene inhibitors

Prior Authorization Group Description:

Oral Immunotherapy Agents PA – Oralair

Drug Name(s)

Oralair

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 allergic rhinitis, with or without conjunctivitis AND
2. Patient's diagnosis is confirmed with ONE of the following:
 - A. Positive skin test to ONE of the pollen extracts included in the requested agent OR
 - B. IgE specific antibodies to ONE of the extracts included in the requested agent: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - B. Patient has an intolerance or hypersensitivity to TWO standard allergy medications, one of which was an intranasal corticosteroid OR
 - C. Patient has an FDA labeled contraindication to TWO standard allergy medications, one of which was an intranasal corticosteroid AND
4. Patient will NOT be using the requested agent in combination with a subcutaneous injectable immunotherapy agent AND
5. The requested agent will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season AND
6. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes AND
7. Patient has been prescribed epinephrine auto-injector for at home emergency use

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Standard allergy medications:

Oral antihistamines, oral corticosteroids, intranasal corticosteroids, intranasal antihistamines, or leukotriene inhibitors

Prior Authorization Group Description:

Oriahnn PA

Drug Name(s)

Oriahnn

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 heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND
2. Patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) AND
3. Patient is premenopausal AND
4. Patient will NOT be using the requested agent in combination with another GnRH antagonist agent [e.g., Orilissa (elagolix), Myfembree (relugolix, estradiol hemihydrate, norethindrone acetate)] for the requested indication AND
5. The requested dose is within FDA labeled dosing for the requested indication AND
6. ONE of the following:
 - A. Patient is initiating therapy with the requested agent OR
 - B. BOTH of the following:
 - i. Patient is continuing therapy with the requested agent and the prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent AND
 - ii. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

For no prior Oriahnn use: 24 months

For Prior Oriahnn use: Remainder of 24 months

Other Criteria:

Prior Authorization Group Description:

Orilissa PA

Drug Name(s)

Orilissa

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 moderate to severe pain associated with endometriosis AND
2. ONE of the following:
 - A. Patient has coexisting dyspareunia AND has not received 6 or more months of therapy with the requested agent OR
 - B. Patient has coexisting moderate hepatic impairment (Child-Pugh Class B) AND has not received 6 or more months of therapy with the requested agent OR
 - C. Patient does not have coexisting dyspareunia or moderate hepatic impairment (Child-Pugh Class B), AND has not received 24 or more months of therapy with the requested agent AND
3. Patient will NOT be using the requested agent in combination with another GnRH antagonist agent [e.g., Oriahnn (elagolix, estradiol, norethindrone acetate), Myfembree (relugolix, estradiol hemihydrate, norethindrone acetate)] for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication AND
5. ONE of the following:
 - A. Patient is initiating therapy with the requested agent OR
 - B. BOTH of the following:
 - i. Patient is continuing therapy with the requested agent and the prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent AND
 - ii. The total duration of treatment with the requested agent has NOT exceeded 6 months per lifetime if patient has coexisting dyspareunia or moderate hepatic impairment, or 24 months per lifetime if the patient does NOT have coexisting dyspareunia or moderate hepatic impairment

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

For no prior Orilissa use and for prior Orilissa use, see Other Criteria for approval

Other Criteria:

No prior Orilissa use: Approve 6 months for coexisting dyspareunia OR moderate hepatic impairment, Approve 24 months for no coexisting condition

Prior Orilissa use: Approve remainder of 6 months for coexisting dyspareunia OR moderate hepatic impairment, Approve remainder of 24 months for no coexisting condition

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:

Osphena PA

Drug Name(s)

Osphena

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:

Otezla PA

Drug Name(s)

Otezla

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. BOTH of the following:
 - A. Patient has ONE of the following diagnoses:
 - i. Plaque psoriasis OR
 - ii. Active psoriatic arthritis AND
 - B. 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
 - iii. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR
 - iv. Patient has tried and had an inadequate response to at least ONE conventional prerequisite agent for the requested indication OR
 - v. Patient has an intolerance or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR
 - vi. Patient has an FDA labeled contraindication to at least ONE conventional prerequisite agent for the requested indication OR
2. Patient has a diagnosis of oral ulcers associated with Behcet's disease (BD)

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 plaque psoriasis, active psoriatic arthritis, or oral ulcers associated with Behcet's disease (BD) AND
3. Patient has had clinical benefit with the requested agent (i.e., slowing of disease progression or decrease in symptom severity and/or frequency)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Formulary conventional agent required for diagnoses of plaque psoriasis or active psoriatic arthritis

Formulary conventional agents for plaque psoriasis include cyclosporine, methotrexate, tazarotene, topical calcitriol, or topical corticosteroids

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

NO prerequisites are required for a diagnosis of oral ulcers associated with Behcet's disease (BD)

Prior Authorization Group Description:

Otrexup PA

Drug Name(s)

Otrexup

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. ONE of the following:
 - A. Patient has tried and had an inadequate response to a generic methotrexate injectable agent OR
 - B. Patient has an intolerance or hypersensitivity to a generic methotrexate injectable agent OR
 - C. Patient has an FDA labeled contraindication to a generic methotrexate injectable agent OR
 - D. Prescriber has provided information that the patient has a physical or a mental disability that would prevent the patient from using a generic methotrexate injectable 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 for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Oxbryta PA

Drug Name(s)

Oxbryta

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 sickle cell disease AND
2. ONE of the following
 - A. Patient has tried and had an inadequate response to maximally tolerated dose of hydroxyurea OR
 - B. Patient has an intolerance or hypersensitivity to hydroxyurea OR
 - C. Patient has an FDA labeled contraindication to hydroxyurea

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of sickle cell disease AND
3. Patient has had clinical benefit with 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:

Oxervate PA

Drug Name(s)

Oxervate

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 neurotrophic keratitis (NK) 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., ophthalmologist, optometrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

Coverage Duration:

Approval will be for 8 weeks

Other Criteria:

Prior Authorization Group Description:

Oxlumo PA

Drug Name(s)

Oxlumo

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 primary hyperoxaluria type 1 (PH1) confirmed by ONE of the following:
 - A. Genetic testing of the AGXT gene indicates a pathogenic mutation OR
 - B. Liver biopsy demonstrates absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity AND
2. The requested agent will be used to lower urinary or plasma oxalate levels 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 primary hyperoxaluria type 1 (PH1) AND
3. The requested agent will be used to lower urinary or plasma oxalate levels AND
4. Patient has had clinical benefit with the requested agent AND
5. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) 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:

Palynziq PA

Drug Name(s)

Palynziq

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of phenylketonuria (PKU) AND
2. Patient has a baseline blood Phe level greater than 600 micromol/L (10 mg/dL) AND
3. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND
4. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of phenylketonuria (PKU) AND
3. ONE of the following:
 - a. Patient's blood Phe levels are being maintained within the acceptable range OR
 - b. Patient has had a decrease in blood Phe level from baseline AND
4. Patient will NOT be using the requested agent in combination with sapropterin for the requested indication AND
5. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Initial approval will be for 9 months, renewal approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Panretin PA

Drug Name(s)

Panretin

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require BOTH of the following:

1. ONE of the following:

- A. Patient has a diagnosis of cutaneous lesions associated with AIDS-related Kaposi's sarcoma (KS) OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

2. ONE of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Panzyga PA

Drug Name(s)

Panzyga

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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) OR

I. Acquired von Willebrand hemophilia AND ONE of the following:

- i. Patient has failed ONE conventional therapy (e.g., desmopressin solution, von Willebrand factor replacement therapy, corticosteroids, cyclophosphamide, FEIBA, or recombinant factor VIIa) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional therapy OR

J. Refractory pemphigus vulgaris AND ONE of the following:

- i. Patient has failed ONE conventional immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, mycophenolate, corticosteroids) OR
- ii. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ONE conventional immunosuppressive therapy OR

2. ONE of the following:

- A. Patient has another FDA labeled indication for the requested agent OR
- B. Patient has an indication that is supported in CMS approved compendia for the requested agent

Indications with 6 months approval duration: Acquired von Willebrand hemophilia, Guillain-Barre Syndrome, Lambert-Eaton myasthenia syndrome, Kawasaki disease, CMV induced pneumonitis in solid organ transplant, Toxic shock syndrome due to invasive group A streptococcus, Toxic epidermal necrolysis and Stevens-Johnson syndrome

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

Prior Authorization Group Description:

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

Posaconazole Susp

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

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:

Praluent PA

Drug Name(s)

Praluent

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

Initial criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND
- 2. ONE of the following:
 - A. Patient has tried and had an inadequate response to a high-intensity statin (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR
 - B. Patient has an intolerance* to TWO different statins (*intolerance is defined as inability to tolerate the lowest FDA approved starting dose of a statin) OR
 - C. Patient has an FDA labeled contraindication to a statin AND
- 3. Patient will NOT be using the requested agent in combination with another PCSK9 agent AND
- 4. ONE of the following:
 - A. Patient has tried and had an inadequate response to Repatha OR
 - B. Patient has an intolerance or hypersensitivity to Repatha OR
 - C. Patient has an FDA labeled contraindication to Repatha

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:

Prolia PA

Drug Name(s)

Prolia

Indications:

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

Off-Label Uses:

Osteopenia (osteoporosis prophylaxis)

Exclusion Criteria:

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of:

1. ONE of:

A. Patient's (pt) sex is male or the pt is postmenopausal with a diagnosis of osteoporosis AND BOTH of:

i. Pt's diagnosis was confirmed by ONE of:

1. A fragility fracture in the hip or spine OR
2. A T-score of -2.5 or lower OR
3. A T-score of -1.0 to -2.5 AND ONE of:
 - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
 - b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
 - c. A FRAX 10-year probability of hip fracture of 3% or greater AND

ii. ONE of:

1. Pt is at a very high fracture risk as defined by ONE of:
 - a. Pt had a recent fracture (within the past 12 months) OR
 - b. Pt had fractures while on FDA approved osteoporosis therapy OR
 - c. Pt has had multiple fractures OR
 - d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
 - e. Pt has a very low T-score (less than -3.0) OR
 - f. Pt is at high risk for falls or has a history of injurious falls OR
 - g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR
2. ONE of:
 - a. Pt's medication history includes use of a bisphosphonate OR
 - b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR

B. Pt is requesting the agent for osteopenia (osteoporosis prophylaxis) AND ALL of:

i. ONE of:

1. Pt's sex is male and the pt is 50 years of age or over OR
2. Pt is postmenopausal AND

- ii. Pt has a T-score between -1.0 to -2.50 AND
- iii. ONE of:
 - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
 - b. 10-year probability of a hip fracture 3% and greater per FRAX OR
 - c. 10-year probability of a major OP-related fracture 20% and greater per FRAX AND
- iv. ONE of:
 - a. Pt's medication history includes use of a bisphosphonate OR

Criteria continues: See Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- C. Pt's sex is a female with a diagnosis of breast cancer who is receiving aromatase inhibitor therapy AND ONE of:
 - i. Pt's medication history includes use of a bisphosphonate OR
 - ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- D. Pt's sex is male with a diagnosis of prostate cancer receiving androgen deprivation therapy (ADT) AND ONE of:
 - i. Pt's medication history includes use of a bisphosphonate OR
 - ii. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate OR
- E. Pt has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of:
 - i. Pt is either initiating or continuing systemic glucocorticoids in a daily dose equivalent to 7.5 mg or greater of prednisone AND
 - ii. Pt is expected to remain on glucocorticoids for at least 6 months AND
 - iii. Pt's diagnosis was confirmed by ONE of:
 - 1. A fragility fracture in the hip or spine OR
 - 2. A T-score of -2.5 or lower OR
 - 3. A T-score of -1.0 to -2.5 AND ONE of the following:
 - a. A fragility fracture of the proximal humerus, pelvis, or distal forearm OR
 - b. A FRAX 10-year probability for major osteoporotic fracture of 20% or greater OR
 - c. A FRAX 10-year probability of hip fracture of 3% or greater AND
 - iv. ONE of:
 - 1. Pt is at a very high fracture risk as defined by ONE of the following:
 - a. Pt had a recent fracture (within the past 12 months) OR
 - b. Pt had fractures while on FDA approved osteoporosis therapy OR

- c. Pt has had multiple fractures OR
- d. Pt had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) OR
- e. Pt has a very low T-score (less than -3.0) OR
- f. Pt is at high risk for falls or has a history of injurious falls OR
- g. Pt has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm OR

2. ONE of:

- a. Pt's medication history includes use of a bisphosphonate OR
- b. Pt has an intolerance, FDA labeled contraindication, or hypersensitivity to a bisphosphonate AND

2. ONE of:

- A. Pt has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR
- B. Pt has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR
- C. Prescriber has indicated that the pt is not at risk for hypocalcemia (not including risk associated with the requested agent) AND

3. Pt will NOT be using the requested agent in combination with a bisphosphonate, another form of denosumab (e.g., Xgeva), romosozumab-aqqg, or parathyroid hormone analog (e.g., abaloparatide, teriparatide) for the requested indication AND

4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

Prior Authorization Group Description:

Promacta PA

Drug Name(s)

Promacta

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ONE of the following:

1. Patient has a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:

- A. Patient has tried and had an insufficient response to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
- B. Patient has an intolerance or hypersensitivity to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
- C. Patient has an FDA labeled contraindication to a corticosteroid or immunoglobulin (IVIg or anti-D) OR
- D. Patient has had an insufficient response to a splenectomy OR

2. Patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:

- A. Patient's platelet count is less than $75 \times 10^9/L$ 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

Letairis

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

- i. Patient's World Health Organization (WHO) functional class is II or greater AND
- ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
- iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
- iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND
- v. ONE of the following:
 - a. The requested agent will be utilized as monotherapy OR
 - b. The request is for ambrisentan for use in combination with Adcirca or Alyq (tadalafil) for dual therapy ONLY OR
 - c. The requested agent will be utilized for add-on therapy to existing monotherapy [dual therapy, except for dual therapy requests for ambrisentan with Adcirca or Alyq (tadalafil)], AND BOTH of the following:
 - 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 - 2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

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

Criteria for renewal approval require ALL of the following:

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

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

3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Bosentan

Drug Name(s)

Bosentan

Tracleer

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

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

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

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

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1, as determined by right heart catheterization, AND ALL of the following:

- i. Patient's World Health Organization (WHO) functional class is II or greater AND
- ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
- iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
- iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

- a. The requested agent will be utilized as monotherapy OR
- b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:
 - 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 - 2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

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

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

3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Opsumit

Drug Name(s)

Opsumit

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be utilized for add-on therapy to existing monotherapy [dual therapy], AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
3. All three agents in the triple therapy are from a different therapeutic class

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Orenitram

Drug Name(s)

Orenitram

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

- i. Patient's World Health Organization (WHO) functional class is II or greater AND
- ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
- iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
- iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND
- v. ONE of the following:
 - a. The requested agent will be utilized as monotherapy OR
 - b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:
 - 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 - 2. The requested agent is in a different therapeutic class OR
 - c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:
 - 1. Patient is WHO functional class III or IV AND
 - 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 - 3. All three agents in the triple therapy are from a different therapeutic class

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Sildenafil

Drug Name(s)

Liqrev

Revatio

Sildenafil

Sildenafil Citrate

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

Concurrently taking another phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] with the requested agent AND FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

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

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

- i. Patient's World Health Organization (WHO) functional class is II or greater AND
- ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
- iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
- iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

- a. The requested agent will be utilized as monotherapy OR
- b. The requested agent will be utilized for add-on therapy to existing monotherapy [dual therapy], AND BOTH of the following:
 - 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 - 2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following:

1. ONE of the following:

i. A prostanoid has been started as one of the agents in the triple therapy OR

ii. Patient has an intolerance or hypersensitivity to a prostanoid OR

iii. Patient has an FDA labeled contraindication to a prostanoid AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

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

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

3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Tadalafil

Drug Name(s)

Adcirca

Alyq

Tadalafil 20Mg Tablet

Tadliq

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

Concurrently taking another phosphodiesterase type 5 (PDE-5) inhibitor [tadalafil (Adcirca, Alyq or Cialis) or sildenafil (Revatio or Viagra)] with the requested agent AND FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

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

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

- i. Patient's World Health Organization (WHO) functional class is II or greater AND
- ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
- iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
- iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND
- v. ONE of the following:
 - a. The requested agent will be utilized as monotherapy OR
 - b. The request is for Adcirca or Alyq (tadalafil) for use in combination with Letairis (ambrisentan) for dual therapy ONLY OR
 - c. The requested agent will be utilized for add-on therapy to existing monotherapy [dual therapy, except for dual therapy requests for Adcirca or Alyq (tadalafil) with Letairis (ambrisentan)], AND BOTH of the following:
 - 1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- d. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) AND ALL of the following:
 1. ONE of the following:
 - i. A prostanoid has been started as one of the agents in the triple therapy OR
 - ii. Patient has an intolerance or hypersensitivity to a prostanoid OR
 - iii. Patient has an FDA labeled contraindication to a prostanoid AND
 2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND
 3. All three agents in the triple therapy are from a different therapeutic class OR
- C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Prior Authorization Group Description:

Pulmonary Hypertension PA – Tyvaso DPI

Drug Name(s)

Tyvaso DPI

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. Patient is WHO functional class III or IV AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

3. All three agents in the triple therapy are from a different therapeutic class OR

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- C. Patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) as determined by right heart catheterization AND ALL of the following:
 - i. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND
 - ii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND
 - iii. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND
 - iv. Patient has a forced vital capacity (FVC) less than 70% of predicted AND
 - v. Patient will continue standard of care therapy for ILD (e.g., Ofev)

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. ONE of the following:
 - A. Patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND the patient will continue standard of care therapy for ILD (e.g., Ofev) OR
 - B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1

Prior Authorization Group Description:

Pulmonary Hypertension PA – Uptravi

Drug Name(s)

Uptravi

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. All three agents in the triple therapy are from a different therapeutic class

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Pulmonary Hypertension PA – Ventavis

Drug Name(s)

Ventavis

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

i. ONE of the following:

- a. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- b. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed AND

ii. Patient has an FDA labeled indication for the requested agent OR

B. Patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization AND ALL of the following:

i. Patient's World Health Organization (WHO) functional class is II or greater AND

ii. Patient has a mean pulmonary arterial pressure greater than 20 mmHg AND

iii. Patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg AND

iv. Patient has a pulmonary vascular resistance greater than or equal to 3 Wood units AND

v. ONE of the following:

a. The requested agent will be utilized as monotherapy OR

b. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), AND BOTH of the following:

1. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

2. The requested agent is in a different therapeutic class OR

c. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), AND ALL of the following:

1. Patient is WHO functional class III or IV AND

2. Patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy AND

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

Age Restriction:**Prescriber Restrictions:**

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

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

Prior Authorization Group Description:

Pyrimethamine PA

Drug Name(s)

Daraprim

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:

Pyrukynd PA

Drug Name(s)

Pyrukynd

Pyrukynd Taper Pack

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require the following:

1. Patient has a diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD)

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 hemolytic anemia with pyruvate kinase deficiency (PKD) 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., hematologist) 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:

Qbrexza PA

Drug Name(s)

Qbrexza

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of primary axillary hyperhidrosis

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:

Quillichew PA

Drug Name(s)

Quillichew Er

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:

Quillivant PA

Drug Name(s)

Quillivant Xr

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:

Quinine PA

Drug Name(s)

Qualaquin

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:

Qulipta PA

Drug Name(s)

Qulipta

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for migraine prophylaxis AND
3. Patient has 4 migraine headaches or more per month AND
4. ONE of the following:
 - A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
 - B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agentOR
 - C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agentAND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for migraine prophylaxis AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Quviviq PA

Drug Name(s)

Quviviq

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:

Radicava PA

Drug Name(s)

Radicava

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 amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] AND
2. ALL of the following:
 - A. Patient is able to perform most activities of daily living AND
 - B. Patient has had the diagnosis of amyotrophic lateral sclerosis (ALS) for a duration of 2 years or less AND
 - C. Patient has a baseline percent predicted forced vital capacity (FVC) of 80% or greater 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 amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] 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:**

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 6 months for initial, 12 months for renewal

Other Criteria:

Prior Authorization Group Description:

Rasuvo PA

Drug Name(s)

Rasuvo

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. BOTH of the following:
 - A. ONE of the following:
 - i. Patient has tried and had an inadequate response to a generic methotrexate injectable agent OR
 - ii. Patient has an intolerance or hypersensitivity to a generic methotrexate injectable agent OR
 - iii. Patient has an FDA labeled contraindication to a generic methotrexate injectable agent OR
 - iv. Prescriber has provided information that the patient has a physical or a mental disability that would prevent the patient from using a generic methotrexate injectable agent AND
 - B. ONE of the following:
 - i. Patient has tried and had an inadequate response to Otrexup (methotrexate) OR
 - ii. Patient has an intolerance or hypersensitivity to Otrexup (methotrexate) OR
 - iii. Patient has an FDA labeled contraindication to Otrexup (methotrexate)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Rayos PA

Drug Name(s)

Rayos

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****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 failed generic oral prednisone AND at least 1 other different generic oral corticosteroid agent (e.g., dexamethasone, methylprednisolone) OR
 - b. Patient has an intolerance or hypersensitivity to generic oral prednisone AND at least 1 other different generic oral corticosteroid agent (e.g., dexamethasone, methylprednisolone) OR
 - c. Patient has an FDA labeled contraindication to generic oral prednisone AND at least 1 other different generic oral corticosteroid agent (e.g., dexamethasone, methylprednisolone)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 6 months

Other Criteria:

Prior Authorization Group Description:

Reblozyl PA

Drug Name(s)

Reblozyl

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. BOTH of the following:

i. Patient has a diagnosis of Beta thalassemia requiring regular red blood cell (RBC) transfusions AND

ii. Patient's diagnosis was confirmed by BOTH of the following:

1. Hemoglobin analysis by hemoglobin electrophoresis or high-performance liquid chromatography AND

2. Genetic analysis for both Beta thalassemia and Alpha thalassemia mutations OR

B. Patient has a diagnosis of anemia associated with myelodysplastic syndrome with ring sideroblasts (MDS-RS) AND BOTH of following:

i. Patient has very low-to-intermediate-risk disease AND

ii. BOTH following:

1. Patient has tried and had an inadequate response to an erythropoiesis stimulating agent (ESA) [e.g., Aranesp (darbepoetin alfa), Epogen/Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] AND

2. Patient has required 2 or more red blood cell (RBC) units over 8 weeks OR

C. Patient has a diagnosis of anemia associated with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) AND BOTH of the following:

i. Patient has very low-to-intermediate-risk disease AND

ii. BOTH of following:

1. Patient has tried and had an inadequate response to an erythropoiesis stimulating agent (ESA) [e.g., Aranesp (darbepoetin alfa), Epogen/Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] AND

2. Patient has required 2 or more red blood cell (RBC) units over 8 weeks 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., hematologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

Coverage Duration:

Initial approval: 15 wks for Beta thalassemia, 12 mos for all other diagnoses. 12 mos 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 Beta thalassemia requiring regular red blood cell (RBC) transfusions

OR

B. Patient has a diagnosis of anemia associated with myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

C. Patient has a diagnosis of anemia associated with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) 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

Prior Authorization Group Description:

Recorlev PA

Drug Name(s)

Recorlev

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 endogenous hypercortisolemia with Cushing's syndrome AND
2. ONE of the following:
 - A. Patient had an inadequate response to pituitary surgical resection OR
 - B. Patient is NOT a candidate for pituitary surgical resection AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to pasireotide OR
 - B. Patient has an intolerance or hypersensitivity to pasireotide OR
 - C. Patient has an FDA labeled contraindication to pasireotide

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 endogenous hypercortisolemia with Cushing's syndrome AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Reditrex PA

Drug Name(s)

Reditrex

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. BOTH of the following:
 - A. ONE of the following:
 - i. Patient has tried and had an inadequate response to a generic methotrexate injectable agent OR
 - ii. Patient has an intolerance or hypersensitivity to a generic methotrexate injectable agent OR
 - iii. Patient has an FDA labeled contraindication to a generic methotrexate injectable agent OR
 - iv. Prescriber has provided information that the patient has a physical or a mental disability that would prevent the patient from using a generic methotrexate injectable agent AND
 - B. ONE of the following:
 - i. Patient has tried and had an inadequate response to Otrexup (methotrexate) OR
 - ii. Patient has an intolerance or hypersensitivity to Otrexup (methotrexate) OR
 - iii. Patient has an FDA labeled contraindication to Otrexup (methotrexate)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication for the requested agent AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Regranex PA

Drug Name(s)

Regranex

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. ONE of the following:

a. BOTH of the following:

i. Patient has a diagnosis of lower extremity diabetic neuropathic ulcer(s) that extends into the subcutaneous tissue or beyond AND

ii. The ulcer(s) intended for treatment has an adequate blood supply OR

b. Patient has an indication that is supported in CMS approved compendia for the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Relexxii PA

Drug Name(s)

Methylphenidate Hydrochloride Er (Relexxii)

Relexxii

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:

Relistor Inj PA

Drug Name(s)

Relistor Inj

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 diagnoses:

A. Patient has opioid-induced constipation (OIC) with advanced illness or pain caused by active cancer and is receiving palliative care OR

B. Patient has opioid induced constipation (OIC) and chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment AND

2. Patient has chronic use of an opioid agent in the past 90 days AND

3. ONE of the following:

A. Patient has tried and had an inadequate response to lactulose OR

B. Patient has an intolerance or hypersensitivity to lactulose OR

C. Patient has an FDA labeled contraindication to lactulose

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Relistor Tablet PA

Drug Name(s)

Relistor Tab

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:

Relyvrio PA

Drug Name(s)

Relyvrio

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 amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease]
AND
2. BOTH of the following:
 - A. Patient's symptom onset was within the past 18 months AND
 - B. Patient has a baseline percent predicted slow vital capacity (SVC) greater than 60%

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 amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease]
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., 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:

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:

Reyvow PA

Drug Name(s)

Reyvow

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:

Rho Kinase Inhibitor PA – Rhopressa

Drug Name(s)

Rhopressa

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

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

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of open-angle glaucoma or ocular hypertension AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Rho Kinase Inhibitor PA – Rocklatan

Drug Name(s)

Rocklatan

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

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

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of open-angle glaucoma or ocular hypertension AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Ritalin LA PA

Drug Name(s)

Methylphenidate Hydrochloride Er (Ritalin LA)

Ritalin La

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:

Ritalin PA

Drug Name(s)

Methylphenidate Hydrochloride (Ritalin)

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)

Daliresp

Roflumilast

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require BOTH of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Samsca PA

Drug Name(s)

Samsca

Tolvaptan

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

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

Required Medical Information:

Criteria for approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 30 days

Other Criteria:

Prior Authorization Group Description:

Sapropterin PA

Drug Name(s)

Javygtor

Kuvan

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
Afinitor
Afinitor Disperz
Alecensa
Alunbrig
Ayvakit
Balversa
Besremi
Bexarotene Cap
Bosulif
Braftovi
Brukinsa
Cabometyx
Calquence
Caprelsa
Cometriq
Copiktra
Cotellic
Daurismo
Erivedge
Erleada
Erlotinib Hydrochloride
Everolimus
Exkivity
Farydak
Fotivda
Gavreto
Gefitinib
Gilotrif
Gleevec
Ibrance
Iclusig
Idhifa
Imatinib Mesylate
Imbruvica
Inlyta
Inqovi
Inrebic
Iressa
Jakafi
Jaypirca

Kisqali
Kisqali Femara 200 Dose
Kisqali Femara 400 Dose
Kisqali Femara 600 Dose
Koselugo
Krazati
Lapatinib Ditosylate
Lenalidomide
Lenvima 10 Mg Daily Dose
Lenvima 12Mg Daily Dose
Lenvima 14 Mg Daily Dose
Lenvima 18 Mg Daily Dose
Lenvima 20 Mg Daily Dose
Lenvima 24 Mg Daily Dose
Lenvima 4 Mg Daily Dose
Lenvima 8 Mg Daily Dose
Lonsurf
Lorbrena
Lumakras
Lynparza
Lytgobi
Matulane
Mekinist
Mektovi
Nerlynx
Nexavar
Ninlaro
Nubeqa
Odomzo
Onureg
Orgovyx
Orserdu
Pemazyre
Piqray 200Mg Daily Dose
Piqray 250Mg Daily Dose
Piqray 300Mg Daily Dose
Pomalyst
Qinlock
Retevmo
Revlimid
Rezlidhia
Rozlytrek
Rubraca
Rydapt

Scemblix
Sorafenib
Sprycel
Stivarga
Sunitinib Malate
Sutent
Tabrecta
Tafinlar
Tagrisso
Talzenna
Tarceva
Targretin Cap
Tasigna
Tazverik
Tepmetko
Thalomid
Tibsovo
Tretinoin 10Mg Cap
Truseltiq
Tukysa
Turalio
Tykerb
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
Yonsa
Zejula
Zelboraf

Zolanza
Zydelig
Zykadia
Zytiga

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 indicationOR
 - c. Patient has an FDA labeled contraindication to the first-line therapy for the requested indication
- AND
- iv. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines AND

Initial criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

Approval will be for 12 months

Other Criteria:

- v. ONE of the following:
 - a. The requested agent is not Bosulif or Tasigna OR
 - b. The requested agent is Bosulif or Tasigna AND ONE of the following:
 1. Patient's medication history indicates use of imatinib OR Sprycel for the requested indication (if applicable) OR

2. Patient has an intolerance or hypersensitivity to imatinib OR Sprycel OR
3. Patient has an FDA labeled contraindication to imatinib OR Sprycel OR
4. CMS approved compendia does not support the use of imatinib OR Sprycel for the requested indication OR
5. Prescriber has provided information in support of use of Bosulif or Tasigna over imatinib OR Sprycel for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND
3. ONE of the following:
 - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 180 days OR
 - B. Prescriber states the patient is currently being treated with the requested agent OR
 - C. ALL of the following:
 - i. Patient has had clinical benefit with the requested agent AND
 - ii. Patient does NOT have any FDA labeled contraindications to the requested agent AND
 - iii. Patient does NOT have any FDA labeled limitations of use that is not otherwise supported in NCCN guidelines

Prior Authorization Group Description:

Signifor LAR PA

Drug Name(s)

Signifor Lar

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 acromegaly AND ONE of the following:

i. Patient had an inadequate response to surgery as indicated by growth hormone and serum IGF-1 levels that are above the reference ranges for the patient's gender and age
OR

ii. Patient is NOT a candidate for surgery OR

B. Patient has a diagnosis of Cushing's disease (CD) AND ONE of the following:

i. Patient had an inadequate response to pituitary surgical resection OR

ii. Patient is NOT a candidate for pituitary surgical resection OR

C. Patient has an indication that is supported in CMS approved compendia for the requested agent

Criteria for renewal approval require BOTH of the following:

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

2. ONE of the following:

A. Patient has a diagnosis of acromegaly AND ONE of the following:

i. Patient has growth hormone and serum IGF-1 levels that are within normal limits for patient's gender and age reference range OR

ii. Patient has had clinical improvement (e.g., reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) OR

B. Patient has a diagnosis of Cushing's disease (CD) AND BOTH of the following:

i. Patient has a urinary free cortisol level less than or equal to the upper limit of normal
AND

ii. Patient has had improvement in at least ONE of the following clinical signs and symptoms:

1. Fasting plasma glucose OR

2. Hemoglobin A1c OR

3. Hypertension OR

4. Weight OR

C. BOTH of the following:

i. Patient has an indication that is supported in CMS approved compendia for the requested agent AND

ii. Patient has had clinical benefit with the requested agent

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

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:

Skyckarys PA

Drug Name(s)

Skyckarys

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require the following:

1. Patient has a diagnosis of Friedreich's ataxia (FA, FRDA) with genetic analysis confirming mutation in the frataxin (FXN) gene

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 Friedreich's ataxia (FA, FRDA) AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

Prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, 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:

Sodium Oxybate PA

Drug Name(s)

Sodium Oxybate

Xyrem

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of narcolepsy with cataplexy OR
- B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following:

- i. ONE of the following:

- a. Patient is under 18 years of age OR

- b. ONE of the following:

- 1. Patient has tried and had an inadequate response to modafinil or armodafinil OR

- 2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR

- 3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

- ii. ONE of the following:

- a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR

- b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR

- c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR

- C. Patient has another indication that is supported in CMS approved compendia for the requested agent

Age Restriction:

Patient is 7 years of age or over

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Somatostatin Analogs PA – Lanreotide

Drug Name(s)

Somatuline Depot

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent 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 180 days OR

B. Prescriber states the patient is currently being treated with the requested agent OR

2. BOTH of the following:

A. ONE of the following:

i. Patient has a diagnosis of acromegaly AND ONE of the following:

a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR

b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR

c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR

ii. Patient has a diagnosis of gastroenteropancreatic neuroendocrine tumors AND BOTH of the following:

a. The tumors are well or moderately differentiated AND

b. ONE of the following:

1. The tumors are unresectable, locally advanced OR

2. Patient has metastatic disease OR

iii. Patient has a diagnosis of carcinoid syndrome OR

iv. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

B. 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. 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. ONE of the following:

1. Patient has a diagnosis of acromegaly OR

2. Patient has a diagnosis of metastatic OR unresectable, locally advanced, well or moderately differentiated gastroenteropancreatic neuroendocrine tumors
OR

3. Patient has a diagnosis of carcinoid syndrome OR

4. Patient has another indication that is supported in CMS approved compendia for the requested agent

AND

ii. Patient has had clinical benefit with the requested agent AND

iii. 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 – Mycapssa

Drug Name(s)

Mycapssa

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. BOTH of the following:

- a. Patient has a diagnosis of acromegaly AND
- b. Patient has responded to and tolerated treatment with octreotide or lanreotide OR
- ii. 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

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 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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

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

Other Criteria:

Prior Authorization Group Description:

Somatostatin Analogs PA – Octreotide

Drug Name(s)

Octreotide Acetate

Sandostatin

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 - Sandostatin LAR

Drug Name(s)

Sandostatin Lar Depot

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 an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND ONE of the following:

- i. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
- ii. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR

B. ONE of the following:

i. Patient has a diagnosis of acromegaly AND ONE of the following:

- a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR
- b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR
- c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by growth hormone levels or serum IGF-1 levels that are above the reference range OR

ii. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR

iii. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR

iv. Patient has a diagnosis of dumping syndrome AND ONE of the following:

- a. Patient has tried and had an inadequate response to acarbose OR
- b. Patient has an intolerance or hypersensitivity to acarbose OR
- c. Patient has an FDA labeled contraindication to acarbose OR

v. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

2. Patient has responded to and tolerated octreotide for a minimum of 2 weeks 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 6 months for initial, 12 months for renewal

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

AND

2. ONE of the following:

A. Patient has a diagnosis of acromegaly OR

B. Patient has severe diarrhea and/or flushing episodes associated with metastatic carcinoid tumors OR

C. Patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR

D. Patient has a diagnosis of dumping syndrome OR

E. Patient has another indication that is supported in CMS approved compendia for the requested agent

AND

3. Patient has had clinical benefit with the requested agent AND

4. The requested dose is within FDA labeled dosing or supported in CMS approved compendia dosing for the requested indication

Prior Authorization Group Description:

Somatostatin Analogs PA – Somavert

Drug Name(s)

Somavert

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of acromegaly AND ONE of the following:

A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR

B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR

C. BOTH of the following:

i. ONE of the following:

a. Patient is not a candidate for surgical resection or pituitary radiation therapy OR

b. The requested agent is for adjunctive therapy with pituitary radiation therapy OR

c. Patient had an inadequate response to surgery or pituitary radiation therapy as indicated by serum IGF-1 levels that are above the reference range AND

ii. ONE of the following:

a. Patient has tried and had an inadequate response to octreotide or Somatuline Depot (lanreotide) OR

b. Patient has an intolerance or hypersensitivity to octreotide or Somatuline Depot (lanreotide) OR

c. Patient has an FDA labeled contraindication to octreotide or Somatuline Depot (lanreotide) AND

2. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

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

2. Patient has a diagnosis of acromegaly AND

3. Patient has had clinical benefit with the requested agent AND

4. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

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

Other Criteria:

Prior Authorization Group Description:

Sovaldi PA

Drug Name(s)

Sovaldi

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. Patient has a diagnosis of hepatitis C confirmed by serological markers AND
2. Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and if positive, will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent AND
3. The requested agent will be used in a treatment regimen and length of therapy that is supported in FDA approved labeling or AASLD/IDSA guidelines for the patient's diagnosis and genotype AND
4. The dosing of the requested agent is within the FDA labeled dosing or supported in AASLD/IDSA guideline dosing for the requested indication AND
5. ONE of the following:
 - A. There is evidence of a claim that the patient has been treated with the requested agent within the past 90 days OR
 - B. Prescriber states the patient has been treated with the requested agent within the past 90 days OR
 - C. Patient has an FDA labeled contraindication or hypersensitivity to TWO preferred agents: Epclusa and Harvoni for supported genotypes OR
 - D. Prescriber has provided information based on FDA approved labeling or AASLD/IDSA guidelines supporting the use of the non-preferred agent for the patient's diagnosis and genotype over TWO preferred agents: Epclusa and Harvoni for supported genotypes

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Spravato PA

Drug Name(s)

Spravato 56Mg Dose

Spravato 84Mg Dose

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require BOTH of the following:

1. BOTH of the following:
 - a. ONE of the following:
 - i. Patient has a diagnosis of treatment-resistant depression (TRD) OR
 - ii. Patient has a diagnosis of major depressive disorder (MDD) with acute suicidal ideation or behavior AND
 - b. The requested agent will be used in combination with an oral antidepressant 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 treatment-resistant depression (TRD) AND
 - b. Patient has tried and had an inadequate response to at least two different oral antidepressants (e.g., SSRIs, SNRIs) OR
 2. Patient has a diagnosis of major depressive disorder (MDD) with acute suicidal ideation or behavior AND
 - ii. Prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist) 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. BOTH of the following:
 - a. ONE of the following:
 - i. Patient has a diagnosis of treatment-resistant depression (TRD) OR

- ii. Patient has a diagnosis of major depressive disorder (MDD) with acute suicidal ideation or behavior AND
 - b. The requested agent will be used in combination with an oral antidepressant 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., psychiatrist) 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:

Strensiq PA

Drug Name(s)

Strensiq

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 ONE of the following diagnoses:

A. Perinatal or infantile-onset hypophosphatasia OR

B. Juvenile-onset hypophosphatasia AND

2. Patient has documentation (i.e., medical records) of clinical manifestations to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6-dependent seizures, skeletal abnormalities such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive") AND

3. Patient has documentation (i.e., medical records) of radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis, fractures) AND

4. Patient has documentation (i.e., medical records) of confirmed mutation(s) in the ALPL gene that encodes the tissue non-specific isoenzyme of alkaline phosphatase (TNSALP)
AND

5. Patient has documentation (i.e., medical records) of a measured total serum alkaline phosphatase (ALP) level that is below the normal lab reference range for age and sex AND

6. Patient has documentation (i.e., medical records) of ONE of the following:

A. Elevated urine concentration of phosphoethanolamine (PEA) OR

B. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR

C. Elevated urinary inorganic pyrophosphate (PPi) AND

7. The requested dose is within FDA labeled dosing (based on the patient's weight) for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Criteria for renewal approval require ALL of the following:

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

AND

2. Patient has ONE of the following diagnoses:
 - A. Perinatal or infantile-onset hypophosphatasia OR
 - B. Juvenile-onset hypophosphatasia AND
3. There is documentation (i.e., medical records) that the patient has had a decrease in at least ONE of the following levels:
 - a. Urine concentration of phosphoethanolamine (PEA) OR
 - b. Serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR
 - c. Urinary inorganic pyrophosphate (PPi) AND
4. Patient has documentation (i.e., medical records) of clinical improvement and/or stabilization with the requested agent (e.g., improvement in respiratory status, growth, pain, radiographic findings, other symptoms associated with the disease)
AND
5. The requested dose is within FDA labeled dosing (based on the patient's weight) for the requested indication

Prior Authorization Group Description:

Substrate Reduction Therapy PA – Cerdelga

Drug Name(s)

Cerdelga

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 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. Patient is a CYP2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) established by a genetic test AND
3. Prescriber has drawn baseline measurements of hemoglobin level, platelet count, liver volume, and spleen volume AND
4. 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:

Substrate Reduction Therapy PA – Miglustat

Drug Name(s)

Miglustat

Zavesca

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:

Sucraid PA

Drug Name(s)

Sucraid

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 congenital sucrase-isomaltase deficiency (CSID) 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 congenital sucrase-isomaltase deficiency (CSID) 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:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Sunosi PA

Drug Name(s)

Sunosi

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 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) OR

B. Patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND ONE of the following:

- i. Patient has tried and had an inadequate response to modafinil or armodafinil OR
- ii. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR
- iii. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

2. Patient will NOT be using the requested agent in combination with modafinil, armodafinil, or a standard stimulant agent (e.g., methylphenidate) for the requested indication AND

3. Patient will NOT be using the requested agent in combination with OR within 14 days of a monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine)

Age Restriction:

Patient is 18 years of age or over

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 following:
 - A. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy OR
 - B. Patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND
3. Patient will NOT be using the requested agent in combination with modafinil, armodafinil, or a standard stimulant agent (e.g., methylphenidate) for the requested indication AND
4. Patient will NOT be using the requested agent in combination with OR within 14 days of a monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine) AND
5. Patient has had clinical benefit with the requested agent

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:

Symproic PA

Drug Name(s)

Symproic

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:

Targretin Gel PA

Drug Name(s)

Bexarotene Gel

Targretin 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:

Tarpeyo PA

Drug Name(s)

Tarpeyo

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 primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND
2. The requested agent will be used to reduce proteinuria AND
3. Patient is at risk of rapid disease progression as shown by ONE of the following:
 - A. A urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g OR
 - B. Proteinuria greater than or equal to 1 g/day AND
4. ONE of the following
 - A. Patient is currently being treated with an ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACE or ARB OR
 - B. Patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACE or ARB OR
 - C. Patient has an FDA labeled contraindication to an ACEI or ARB, or a combination medication containing an ACE or ARB AND
5. Patient has not previously been treated with a course of therapy (10 months) with the requested agent AND
6. 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., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

Coverage Duration:

No prior Tarpeyo use, approve 10 months. Prior use - see Other Criteria.

Other Criteria:

Prior Tarpeyo use, approve remainder of 10 months total course of therapy.

Prior Authorization Group Description:

Tavalisse PA

Drug Name(s)

Tavalisse

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 chronic immune (idiopathic) thrombocytopenia (ITP) AND
2. ONE of the following:
 - A. Patient has tried and had an insufficient response to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - B. Patient has an intolerance or hypersensitivity to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - C. Patient has an FDA labeled contraindication to a corticosteroid, another thrombopoietin receptor agonist (e.g., Promacta), or immunoglobulin (IVIg or anti-D) OR
 - D. Patient has had an insufficient response to a splenectomy

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. Patient has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
 - A. Patient's platelet count is $50 \times 10^9/L$ or greater OR
 - B. Patient's platelet count has increased sufficiently to avoid clinically significant bleeding

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

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

Other Criteria:

Prior Authorization Group Description:

Tavneos PA

Drug Name(s)

Tavneos

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

Severe hepatic impairment (Child-Pugh C)

Required Medical Information:

Criteria for approval require BOTH of the following:

1. Patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) AND
2. Patient will continue standard therapy (e.g., corticosteroids, azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication

Age Restriction:**Prescriber Restrictions:**

Prescriber is a specialist in the area of the patient's diagnosis (e.g., 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:

Tegsedi PA

Drug Name(s)

Tegsedi

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 polyneuropathy of hereditary transthyretin-mediated amyloidosis 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, 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:

Teriparatide PA

Drug Name(s)

Forteo

Teriparatide

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

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

Criteria continues: see Other Criteria

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

5. The requested dose is within FDA labeled dosing for the requested indication AND

6. ONE of the following:

A. Patient has never received treatment with teriparatide or Tymlos (abaloparatide) OR

B. Patient has been previously treated with teriparatide or Tymlos (abaloparatide) AND ONE of the following:

i. The total cumulative duration of treatment with teriparatide and Tymlos (abaloparatide) has NOT exceeded 2 years OR

ii. Patient has received 2 years or more of treatment with teriparatide, and remains at or has returned to having a high risk for fracture

Prior teriparatide and/or Tymlos use approve remainder of 2 years of total cumulative therapy. Approve 1 year if patient has received 2 years or more teriparatide

Prior Authorization Group Description:

Tetrabenazine PA

Drug Name(s)

Tetrabenazine

Xenazine

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 agentAND
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 suicidalAND
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:

Tlando PA

Drug Name(s)

Tlando

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's sex is male with a diagnosis of primary or secondary (hypogonadotropic) hypogonadism AND
2. 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 for 12 months

Other Criteria:

Prior Authorization Group Description:

Tobi Podhaler PA

Drug Name(s)

Tobi Podhaler

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Tobramycin neb PA

Drug Name(s)

Kitabis Pak

Tobi

Tobramycin Neb

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

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

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

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Topical Diclofenac 3% Gel PA

Drug Name(s)

Diclofenac Sodium 3% Gel

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of actinic keratosis (AK)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 3 months

Other Criteria:

Prior Authorization Group Description:

Topical Doxepin PA

Drug Name(s)

Doxepin Hydrochloride

Prudoxin

Zonalon

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. ONE of the following:

a. Patient has a diagnosis of moderate pruritus associated with atopic dermatitis AND ONE of the following:

i. Patient has tried and had an inadequate response to a topical corticosteroid (e.g., hydrocortisone, triamcinolone) OR

ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid OR

iii. Patient has an FDA labeled contraindication to a topical corticosteroid OR

b. Patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following:

i. Patient has tried and had an inadequate response to a topical corticosteroid (e.g., hydrocortisone, triamcinolone) OR

ii. Patient has an intolerance or hypersensitivity to a topical corticosteroid OR

iii. Patient has an FDA labeled contraindication to a topical corticosteroid

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 8 days

Other Criteria:

Prior Authorization Group Description:

Topical NSAID PA – Flector

Drug Name(s)

Diclofenac Epolamine

Flector

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 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:**

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

Other Criteria:

Prior Authorization Group Description:

Topical NSAID PA – Licart

Drug Name(s)

Licart

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 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:**

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

Other Criteria:

Prior Authorization Group Description:

Topical NSAID PA – Pennsaid

Drug Name(s)

Diclofenac Sodium (Pennsaid)

Pennsaid

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 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:**

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

Other Criteria:

Prior Authorization Group Description:

Topical Retinoids PA – Adapalene

Drug Name(s)

Adapalene

Adapalene Pump

Differin

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 – Tazarotene

Drug Name(s)

Arazlo

Fabior

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)

Altreno

Atralin

Avita

Retin-A

Retin-A Micro

Retin-A Micro Pump

Tretinoin Cream, Gel

Tretinoin Microsphere

Tretinoin Microsphere Pump

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 – Trifarotene

Drug Name(s)

Aklief

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:

Trezipire PA

Drug Name(s)

Trezipire

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of severe asthma AND
2. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND
3. Patient will NOT be using the requested agent in combination with Xolair, an IL-5 inhibitor (Cinqair, Fasenra, Nucala), or Dupixent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of severe asthma AND
3. Patient is currently being treated with AND will continue asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline) in combination with the requested agent AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with Xolair, an IL-5 inhibitor (Cinqair, Fasenra, Nucala), or Dupixent for the requested indication

Age Restriction:

Patient is 12 years of age or over

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Trientine PA

Drug Name(s)

Clovique

Syprine

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:

Trudhesa PA

Drug Name(s)

Trudhesa

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:

Tymlos PA

Drug Name(s)

Tymlos

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ALL of the following:

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

Age Restriction:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

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

Prior Authorization Group Description:

Tyrvaya PA

Drug Name(s)

Tyrvaya

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:

Ubrelvy PA

Drug Name(s)

Ubrelvy

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for the treatment of acute migraine with or without aura AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent OR
 - B. Patient has an intolerance, or hypersensitivity to a triptan OR
 - C. Patient has an FDA labeled contraindication to a triptan AND
4. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for the treatment of acute migraine with or without aura AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Urea Cycle Disorders PA – Pheburane

Drug Name(s)

Pheburane

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 urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) AND
2. The requested agent will be used as chronic management of UCDs AND
3. The requested dose is within FDA labeled dosing for the requested indication

Age Restriction:**Prescriber Restrictions:**

Prescriber is a specialist (e.g., geneticist, metabolic disorders) or the prescriber has consulted with a specialist

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Urea Cycle Disorders PA – Ravicti

Drug Name(s)

Ravicti

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 urea cycle disorder and the requested agent will be used for chronic management 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:

Urea Cycle Disorders PA - Sodium Phenylbutyrate

Drug Name(s)

Buphenyl

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:

Vtama PA

Drug Name(s)

Vtama

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 plaque psoriasis AND
2. ONE of the following:
 - a. Patient has tried and failed a topical corticosteroid (e.g., triamcinolone) OR
 - b. Patient has an intolerance or hypersensitivity to a topical steroid OR
 - c. Patient has an FDA labeled contraindication to a topical steroid AND
3. ONE of the following:
 - a. Patient has tried and failed a topical vitamin D analog (e.g., calcipotriene) OR tazarotene OR
 - b. Patient has an intolerance or hypersensitivity to a topical vitamin D analog OR tazarotene OR
 - c. Patient has an FDA labeled contraindication to a topical vitamin D analog OR tazarotene

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 plaque psoriasis 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., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Viberzi PA

Drug Name(s)

Viberzi

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Vijoice PA

Drug Name(s)

Vijoice

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 PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing indicating a mutation in the PIK3CA gene AND
2. Patient has severe manifestations of PROS AND
3. Patient requires systemic therapy

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) AND
3. Patient has severe manifestations of PROS AND
4. Patient requires systemic therapy AND
5. Patient has had clinical benefit with 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:

Vivjoa PA

Drug Name(s)

Vivjoa

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 vulvovaginal candidiasis AND
2. The requested agent will be used to reduce the incidence of recurrent vulvovaginal candidiasis AND
3. ONE of the following:
 - A. Patient has tried and had an inadequate response to fluconazole OR
 - B. Patient has an intolerance or hypersensitivity to fluconazole OR
 - C. Patient has an FDA labeled contraindication to fluconazole OR
 - D. Patient will be using fluconazole as part of the fluconazole/Vivjoa dosage regimen for the current infection

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 4 months

Other Criteria:

Prior Authorization Group Description:

Voriconazole PA

Drug Name(s)

Vfend

Vfend Iv

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:

Voxzogo PA

Drug Name(s)

Voxzogo

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 achondroplasia AND
2. The requested agent will be used to increase linear growth AND
3. Patient has open epiphyses

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 achondroplasia AND
3. The requested agent will be used to increase linear growth AND
4. Patient has open epiphyses AND
5. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Vyepti PA

Drug Name(s)

Vyepti

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of migraine AND
2. The requested agent is being used for migraine prophylaxis AND
3. Patient has 4 migraine headaches or more per month AND
4. ONE of the following:
 - A. Patient has tried and had an inadequate response to a conventional migraine prophylaxis agent [e.g., beta blockers (propranolol), anticonvulsants (divalproex, topiramate)] OR
 - B. Patient has an intolerance, or hypersensitivity to a conventional migraine prophylaxis agentOR
 - C. Patient has an FDA labeled contraindication to a conventional migraine prophylaxis agentAND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of migraine AND
3. The requested agent is being used for migraine prophylaxis AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Vyndamax PA

Drug Name(s)

Vyndamax

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Vyndaqel PA

Drug Name(s)

Vyndaqel

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for initial approval require ALL of the following:

1. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
2. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
3. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND
3. The requested agent will be used to reduce cardiovascular mortality and cardiovascular-related hospitalization AND
4. Patient has had clinical benefit with the requested agent AND
5. Patient will NOT be using the requested agent in combination with another tafamidis agent for the requested indication

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Wakix PA

Drug Name(s)

Wakix

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of narcolepsy with cataplexy OR
- B. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND BOTH of the following:

- i. ONE of the following:

- 1. Patient has tried and had an inadequate response to modafinil or armodafinil OR
 - 2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR
 - 3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

- ii. ONE of the following:

- 1. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR
 - 2. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR
 - 3. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate)

Criteria for renewal approval require ALL of the following:

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

2. ONE of the following:

- A. Patient has a diagnosis of narcolepsy with cataplexy OR
- B. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND

3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is 18 years of age or over

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Winlevi PA

Drug Name(s)

Winlevi

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

Requested agent will be used for cosmetic purposes

Required Medical Information:

Criteria for approval require the following:

1. Patient has a diagnosis of acne vulgaris

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:

Xembify PA

Drug Name(s)

Xembify

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. 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., Aubagio, Avonex, Betaseron, Copaxone, dimethyl fumarate, Gilenya, glatiramer, Glatopa, Mavenclad, Mayzent, Plegridy, Rebif, Tecfidera, Vumerity) 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

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:

Xermelo PA

Drug Name(s)

Xermelo

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 carcinoid syndrome diarrhea AND
2. Patient has tried and had an inadequate response to treatment with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) AND
3. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide])

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of carcinoid syndrome diarrhea AND
3. Patient has had clinical benefit with the requested agent (e.g., reduction in the average number of daily bowel movements) AND
4. The requested agent will be used in combination with a somatostatin analog (e.g., Sandostatin [octreotide], Sandostatin LAR [octreotide], Somatuline Depot [lanreotide])

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Xgeva PA

Drug Name(s)

Xgeva

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

1. ONE of the following:

A. Patient has a diagnosis of multiple myeloma AND BOTH of the following:

i. The requested agent will be used for the prevention of skeletal-related events AND

ii. ONE of the following:

1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR

2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR

3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR

B. Patient has a diagnosis of prostate cancer AND ALL of the following:

i. The requested agent will be used for the prevention of skeletal-related events AND

ii. Patient has bone metastases AND

iii. ONE of the following:

1. Patient has a pretreatment or current calcium level that is NOT below the limits of the testing laboratory's normal range OR

2. Patient has a pretreatment or current calcium level that is below the limits of the testing laboratory's normal range AND it will be corrected prior to use of the requested agent OR

3. Prescriber has indicated that the patient is not at risk for hypocalcemia (not including risk associated with the requested agent) OR

Criteria continues: see Other Criteria

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

Approval will be for 12 months

Other Criteria:

C. Patient has a solid tumor cancer diagnosis (e.g., thyroid, non-small cell lung, kidney cancer, or breast cancer) AND ALL of the following:

i. The requested agent will be used for the prevention of skeletal-related events AND

ii. Patient has bone metastases AND

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

Prior Authorization Group Description:

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, Fasenra, Nucala) for the requested indication AND
- 3. The requested dose is within FDA labeled dosing for the requested indication

Criteria for renewal approval require ALL of the following:

- 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
- 2. ONE of the following:
 - A. Patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following:

- i. Patient's weight is within the FDA indicated range for their age (i.e., 20 kg to 150 kg for patients age 6 to less than 12 years and 30 kg to 150 kg for patients 12 years of age or over) AND
- ii. Patient has had clinical benefit with the requested agent AND
- iii. ONE of the following:
 - a. Patient is currently being treated with standard therapy (such as a combination of an ICS, LABA, LAMA, LTRA, theophylline, oral corticosteroid or an oral beta-2 agonist tablet) OR
 - b. Patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a standard therapy OR
- B. Patient has a diagnosis of chronic idiopathic urticaria AND the following:
 - a. Patient has had clinical benefit with the requested agent OR
- C. Patient has a diagnosis of nasal polyps AND the following:
 - a. Patient has had clinical benefit with the requested agent AND
- 3. The requested agent will NOT be used in combination with Dupixent or an injectable interleukin 5 (IL-5) inhibitor (e.g., Cinqair, Fasenra, Nucala) for the requested indication AND
- 4. The requested dose is within FDA labeled dosing for the requested indication

Prior Authorization Group Description:

Xywav PA

Drug Name(s)

Xywav

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require the following:

1. ONE of the following:

- A. Patient has a diagnosis of narcolepsy with cataplexy OR
- B. Patient has a diagnosis of narcolepsy with excessive daytime sleepiness AND BOTH of the following:

- i. ONE of the following:

- a. Patient is under 18 years of age OR

- b. ONE of the following:

- 1. Patient has tried and had an inadequate response to modafinil or armodafinil OR
 - 2. Patient has an intolerance or hypersensitivity to modafinil or armodafinil OR
 - 3. Patient has an FDA labeled contraindication to modafinil or armodafinil AND

- ii. ONE of the following:

- a. Patient has tried and had an inadequate response to ONE standard stimulant agent (e.g., methylphenidate) OR
 - b. Patient has an intolerance or hypersensitivity to ONE standard stimulant agent (e.g., methylphenidate) OR
 - c. Patient has an FDA labeled contraindication to ONE standard stimulant agent (e.g., methylphenidate) OR
 - C. Patient has a diagnosis of idiopathic hypersomnia OR
 - D. Patient has another indication that is supported in CMS approved compendia for the requested agent

Age Restriction:

For diagnosis of narcolepsy with cataplexy, patient is 7 years of age or over. For diagnosis of narcolepsy with excessive daytime sleepiness, patient is 7 years of age or over. For diagnosis of idiopathic hypersomnia, patient is 18 years of age or over.

Prescriber Restrictions:**Coverage Duration:**

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Zepatier PA

Drug Name(s)

Zepatier

Indications:

All Medically-Accepted Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for approval require ALL of the following:

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

Age Restriction:**Prescriber Restrictions:**

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

Coverage Duration:

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

Other Criteria:

Prior Authorization Group Description:

Zokinvy PA

Drug Name(s)

Zokinvy

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:**

FDA labeled contraindications to the requested agent

Required Medical Information:

Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

- i. Patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) AND
- ii. Genetic testing has confirmed a pathogenic variant in the LMNA gene that results in production of progerin OR

B. Patient has a diagnosis of processing-deficient progeroid laminopathy AND ONE of the following:

- i. Genetic testing has confirmed heterozygous LMNA mutation with progerin-like protein accumulation OR
- ii. Genetic testing has confirmed homozygous or compound heterozygous ZMPSTE24 mutations

Criteria for renewal approval require ALL of the following:

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

2. Patient has a diagnosis of ONE of the following:

- A. Hutchinson-Gilford progeria syndrome (HGPS) OR
- B. Processing-deficient progeroid laminopathies with either: heterozygous LMNA mutation with progerin-like protein accumulation OR homozygous or compound heterozygous ZMPSTE24 mutations AND

3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

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

Coverage Duration:

Approval will be for 12 months

Other Criteria:

Prior Authorization Group Description:

Zoryve PA

Drug Name(s)

Zoryve

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 plaque psoriasis AND
2. ONE of the following:
 - a. Patient has tried and failed a topical corticosteroid (e.g., triamcinolone) OR
 - b. Patient has an intolerance or hypersensitivity to a topical steroid OR
 - c. Patient has an FDA labeled contraindication to a topical steroid AND
3. ONE of the following:
 - a. Patient has tried and failed a topical vitamin D analog (e.g., calcipotriene) OR tazarotene OR
 - b. Patient has an intolerance or hypersensitivity to a topical vitamin D analog OR tazarotene OR
 - c. Patient has an FDA labeled contraindication to a topical vitamin D analog OR tazarotene

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 plaque psoriasis AND
3. Patient has had clinical benefit with the requested agent

Age Restriction:

Patient is within the FDA labeled age for the requested agent

Prescriber Restrictions:

Prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) 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:

Zyclara PA

Drug Name(s)

Imiquimod (Zyclara)

Imiquimod Pump

Zyclara

Zyclara Pump

Indications:

All FDA-Approved Indications.

Off-Label Uses:**Exclusion Criteria:****Required Medical Information:**

Criteria for approval require ONE of the following:

1. Patient has a diagnosis of actinic keratosis OR
2. Patient has a diagnosis of external genital and/or perianal warts/condyloma acuminata AND the requested agent is Zyclara/imiquimod 3.75%

Age Restriction:**Prescriber Restrictions:****Coverage Duration:**

External genital and/or perianal warts/condyloma acuminata: 8 weeks

Actinic keratosis: 6 weeks

Other Criteria: