# ACROMEGALY THERAPY

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis including supporting lab/diagnostic test results. Documentation of all past treatments for acromegaly. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For Acromegaly, must be prescribed by an Endocrinologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of acromegaly in patients who have had inadequate response to surgery or radiation and have had inadequate response with generic injectable octreotide. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTEMRA

## Products Affected

- Actemra ACTPen
- Actemra subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of moderate to severe rheumatoid arthritis for patients with documented failure to two of the following alternatives: Enbrel, Humira, Orencia, Rinvoq, Xeljanz/XR. Actemra will be approved for systemic juvenile idiopathic arthritis. Actemra will be approved for polyarticular juvenile idiopathic arthritis for patients with documented failure of both Enbrel and Humira. Covered for the diagnosis of giant cell arteritis. Approved for Systemic Sclerosis-associated Interstitial Lung disease (SSC-ILD). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTHAR

## Products Affected

- Acthar
- Cortrophin Gel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | For all FDA approved indications in adults, documentation of contraindication to, serious side effects (such as steroid-induced mania or sepsis) from, or therapeutic failure with oral or injectable corticosteroids is required. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTIMMUNE

## Products Affected

- Actimmune

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTINIC KERATOSIS

## Products Affected

- Klisyri

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a Dermatologist or Oncologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of actinic keratosis on the face or scalp who have had previous trial and failure or severe intolerance with generic imiquimod 5% cream and either generic fluorouracil 5% cream or generic fluorouracil solution. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACUTE HAE

## Products Affected

- Berinert intravenous kit
- icatibant
- Ruconest
- Sajazir

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for the prophylaxis of hereditary angioedema attacks. Ruconest is also excluded for the treatment of acute laryngeal hereditary angioedema attacks. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by allergist, immunologist, hematologist, or dermatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a confirmed diagnosis of HAE Type 1, Type II, or Type III for the treatment of acute hereditary angioedema attacks. Coverage of Berinert, Ruconest, and Sajazir requires documentation of inadequate response or severe intolerance to icatibant (generic for Firazyr). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADEMPAS

## Products Affected

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | For pulmonary hypertension: results of a right heart catheterization, current and previous therapies for this diagnosis. For chronic thromboembolic pulmonary hypertension (CTEPH): documentation of diagnosis and surgical history (if applicable). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist or cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of pulmonary hypertension diagnosed by right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest. In addition, the patient must have a pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. There must also be documentation of clinical failure or severe intolerance to generic sildenafil or tadalafil/Alyq and one other agent with a different mechanism of action, such as a prostacyclin or an endothelin receptor antagonist. Covered for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) when the patient has documentation of recurrent or persistent disease after surgical treatment or documentation of inoperable disease. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ALPHA-1 ANTITRYPSIN THERAPY

## Products Affected

- Aralast NP intravenous recon soln 1,000 mg
- Glassia
- Prolastin-C intravenous solution
- Zemaira intravenous recon soln 1,000 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results (such as AAT serum levels, genotype testing, and pulmonary function testing, or other tests performed to confirm the diagnosis, and documentation of previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist |
| **Coverage Duration** | One year, only as weekly infusions |
| **Other Criteria** | Coverage will not be provided for alpha antitrypsin deficits other than the ones defined here: patients with alpha 1 antitrypsin (AAT) levels below 11 micromol/L (80mg/dL or approximately 57mg/dL by nephelometry) who are PiZZ, PiSZ, PiZ(null), Pi(null)(null), Pi(malton,malton), Pi(Siiyama,Siiyama) or have dysfunctional AAT protein (such as PiF or Pi Pittsburg genotypes) AND have evidence of emphysema as FEV1 less than 80% of predicted value. Patients must also demonstrate 1 or more of the following: signs of significant lung disease such as chronic productive cough or unusual frequency of lower respiratory infection, airflow obstruction, accelerated decline of FEV1 or chest radiograph or CT scan evidence of emphysema, especially in the absence of a recognized risk factor (smoking, occupational dust exposure, etc.). In addition, patients with emphysema due to AAT deficiency must be maintained on regimens similar to those patients with emphysema not associated with AAT deficiency, including: maximally tolerated doses of beta-adrenergic bronchodilators, anticholinergics and antibiotics, when appropriate and no contraindications exist. Patients must also have vaccinations against influenza and pneumococcus. Request will also be evaluated for Part B vs |

| PA Criteria | Criteria Details |
|---|---|
| | Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AMPHETAMINE

## Products Affected

- amphetamine sulfate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used for weight loss, even if non-cosmetic (such as morbid obesity). |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# APOMORPHINE

## Products Affected

- apomorphine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Apomorphine (generic for Apokyn) is covered for the treatment of off episodes in Parkinson's disease patients established on levodopa/carbidopa therapy. Patient must have documented attempts at levodopa/carbidopa dose and/or frequency adjustment, up to a maximum tolerated dose is achieved or intolerance is experienced, to mitigate wearing-off symptoms. Recertification for the treatment of off episodes will require objective and/or subjective evidence from prescriber of a decrease in frequency and/or severity of wearing-off symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used for the treatment of patients with non-refractory mycobacterium avium complex (MAC) disease or when being used as a single agent. |
| **Required Medical Information** | Diagnosis, current and previous therapies, pertinent lab/diagnostic test results. For the diagnosis of refractory mycobacterium avium complex disease, sputum culture results are required. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an infectious disease specialist or pulmonologist. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for patients with refractory mycobacterium avium complex (MAC) disease who have documentation of a positive sputum culture, obtained after a minimum 6-month treatment with a multi-drug regimen (such as clarithromycin/azithromycin, rifampin, and ethambutol). For approval, patient must be using Arikayce in combination with other medications as part of a multi-drug regimen. Recertification will require documentation of a negative sputum culture while taking Arikayce taken within 30 days prior to the request. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AURYXIA

## Products Affected

- Auryxia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for a diagnosis of iron deficiency anemia, as iron products are excluded from Part D coverage. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Auryxia will be covered for the control of serum phosphorus levels for patients with chronic kidney disease on dialysis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AUSTEDO

## Products Affected

- Austedo oral tablet 12 mg, 6 mg, 9 mg
- Austedo XR oral tablet extended release 24 hr 12 mg, 24 mg, 30 mg, 36 mg, 42 mg, 48 mg, 6 mg
- Austedo XR Titration Kt(Wk1-4) oral tablet, Ext Rel 24hr dose pack 6 mg (14)-12 mg (14)-24 mg (14)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Will not be covered in combination with tetrabenazine (Xenazine). |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or a psychiatrist |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BEHAVIORAL HEALTH

## Products Affected

- Abilify MyCite Maintenance Kit oral tablet with sensor and strip 15 mg, 2 mg, 20 mg, 30 mg, 5 mg
- Abilify MyCite Starter Kit oral tablet with sensor, strip, pod 10 mg
- asenapine maleate
- Auvelity
- Caplyta oral capsule 10.5 mg, 21 mg, 42 mg
- Fanapt
- Lybalvi oral tablet 10-10 mg, 15-10 mg, 20-10 mg, 5-10 mg
- Rexulti oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
- Secuado
- Vraylar oral capsule

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Lybalvi also excluded for patients using opioids or undergoing acute opioid withdrawal. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | For a dx of bipolar disorder, coverage of asenapine (generic for Saphris), Caplyta, Fanapt or Vraylar requires documentation of significant intolerance or therapeutic failure of two generic first-line treatments (such as lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For a dx of schizophrenia, coverage of asenapine (generic for Saphris), Caplyta, Fanapt, Rexulti, Secuado, or Vraylar requires documentation of significant intolerance or therapeutic failure of two generic first-line treatments (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Coverage of Lybalvi for a dx of schizophrenia or bipolar 1 disorder requires documentation of one of the following: 1) at least a 4-week trial with generic olanzapine that yielded beneficial stable clinical response but unacceptable weight gain (unacceptability as determined by provider with attribution to side effect of olanzapine) or 2) significant intolerance or therapeutic failure of two generic first-line treatments (such as lurasidone, |

| PA Criteria | Criteria Details |
|---|---|
| | lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For a dx of major depressive disorder, coverage of Auvelity, Rexulti, or Vraylar requires documentation of significant intolerance or therapeutic failure of an antidepressant (such as an SSRI, SNRI, TCA, bupropion) and a generic atypical antipsychotic indicated for major depressive disorder (such as aripiprazole, olanzapine, quetiapine), used alone or in combination. Abilify Mycite is covered for schizophrenia, bipolar I disorder, or major depressive disorder in patients who have had severe intolerance or drug failure with generic aripiprazole tablets and long-acting injectable aripiprazole (e.g., Abilify Maintena). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BENLYSTA

## Products Affected

- Benlysta subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for patients who are currently receiving treatment with any B-cell-targeted therapy or biologic. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be followed by a Rheumatologist or Nephrologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy and patients with active lupus nephritis who are receiving standard therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BESREMI

## Products Affected

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. If patient is currently taking hydroxyurea, they must transition off by gradual taper and discontinue by week 13. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or hematologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of polycythemia vera (PV). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BEXAROTENE GEL

## Products Affected

- bexarotene topical

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or dermatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of refractory or persistent cutaneous t-cell lymphoma (CTCL) (stage 1a or 1b) after failure with or inability to tolerate at least one other therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BTKI

## Products Affected

- Brukinsa
- Calquence
- Calquence (acalabrutinib mal)
- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral suspension
- Imbruvica oral tablet 420 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For cancer diagnosis, must be prescribed by an Oncologist or Hematologist. For non-cancer diagnosis, must be prescribed by an appropriate specialist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for FDA-approved indications. For shared indications, approval of Calquence requires intolerance or contraindication to Brukinsa and Imbruvica. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BUDESONIDE FOAM

## Products Affected

- budesonide rectal

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a gastroenterologist |
| **Coverage Duration** | Initial approval - 6 weeks. Subsequent courses will be authorized at 6-week intervals. |
| **Other Criteria** | Budesonide foam will be authorized for patients with a diagnosis of active, mild to moderate ulcerative colitis with documentation of severe intolerance or therapeutic failure to mesalamine enemas, mesalamine suppositories, or hydrocortisone enemas. The initial approval will be for six weeks. As topical budesonide does not have proven efficacy to maintain remission, chronic therapy with budesonide foam will not be authorized. Approval for future treatment courses will require documentation of remission from the initial course of therapy. In addition, documentation that remission failed on a course of an appropriate immunomodulator or biologic will be required. If the criteria are met, subsequent treatment courses will a be approved in 6-week intervals. Requests will also be evaluated for off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BYLVAY

## Products Affected

- Bylvay

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of liver transplant, clinical evidence of decompensated cirrhosis or as limited by FDA labeling |
| **Required Medical Information** | Diagnosis of Alagille syndrome or PFIC confirmed by genetic testing, objective and/or subjective provider assessment of baseline pruritus severity. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hepatologist, gastroenterologist, or physician knowledgeable in the management of progressive familial intrahepatic cholestasis (PFIC). |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for the treatment of cholestatic pruritus in patients at least 12 months of age who have Alagille syndrome with confirmed mutations in the JAG1 or NOTCH2 gene. Covered for treatment of significant pruritus due to progressive familial intrahepatic cholestasis (PFIC). Significant is defined as severe enough pruritus that sleep and/or activities of daily living are disturbed. Recertification for both indications requires documentation that the patient is tolerating therapy and is experiencing a decrease in pruritis from baseline based on objective and/or subjective assessment from provider. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CABLIVI

## Products Affected

- Cablivi injection kit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist |
| **Coverage Duration** | Initial approval - 3 months. Recertification - 1 month. |
| **Other Criteria** | Covered for patients with a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) when being used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab). Should documentation of underlying disease persist (such as suppressed ADAMTS13 activity levels) after the initial treatment period (up to 30 days beyond the last plasma exchange), recertification will be approved for an additional 1 month of therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CAMZYOS

## Products Affected

- Camzyos

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by a cardiologist. |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Covered for patients with a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) confirmed by echocardiogram AND/OR cardiac magnetic resonance. Must have New York Heart Association (NYHA) Class II or Class III functional status and a left ventricular ejection fraction (LVEF) of at least 55%. In addition, the patient must have had serious side effects or drug failure to at least one non-vasodilating beta blocker (i.e. atenolol, bisoprolol, metoprolol) AND one non-dihydropyridine calcium channel blocker (must be separate trials), unless there is a documented medical reason why these agents cannot be used. Recertification will require 1) submission of progress notes documenting the patient has achieved/maintained a positive clinical response to therapy AND 2) the patient's LVEF is at least 50%. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CARBAGLU

## Products Affected

- carglumic acid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for acute or chronic hyperammonemia due to the deficiency of the hepatic enzyme n-acetylglutamate synthase (NAGS). Covered as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CERDELGA

## Products Affected

- Cerdelga

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with Cerdelga and enzyme replacement therapy (such as Eleyso, Cerezyme) is excluded. Concomitant use of a moderate or strong CYP2D6 inhibitor with a moderate or strong CYP3a inhibitor in extensive metabolizers or intermediate metabolizers is excluded. Concomitant use of a strong CYP3a inhibitor in poor metabolizers or intermediate metabolizers is excluded. Cerdelga is excluded in patients with pre-existing cardiac disease, long Q-T syndrome, and for those who take class 1a or class III antiarrhythmic. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results (such as enzyme analysis, mutation analysis, or bone marrow studies, or other tests performed to confirm the diagnosis). Current drug profile to avoid labeled exclusions for use with enzyme replacement therapy, strong CYP3a inhibitors, and certain antiarrhythmics. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Cerdelga is covered for Type 1 Gaucher disease in patients who are CYP2D6 extensive metabolizers, intermediate metabolizers or poor metabolizers. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CGRP ANTAGONISTS

## Products Affected

- Aimovig Autoinjector
- Ajovy Autoinjector
- Ajovy Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for a diagnosis of episodic or chronic migraine headache. Patient must be experiencing 4 or more migraine headache days per month. Patient must have been treated with two different classes of medications, for at least eight weeks per trial, that are supported by compendia for the prophylactic treatment of migraine headache (such as amitriptyline, divalproex sodium, propranolol, topiramate, or venlafaxine) which resulted in intolerance or lack of clinical efficacy. For clinical failure due to intolerance, an eight-week trial of medication is not required. Upon recertification, prescriber must attest to the clinical response to treatment, defined as a reduction in the number of migraine headache days per month compared to pre-treatment. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CHOLBAM

## Products Affected

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis and pertinent lab/diagnostic test results (such as gas chromatography-mass spectrometry urine analysis, liver function tests and other tests performed to confirm the diagnosis). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist, gastroenterologist, geneticist, hepatologist, or metabolic specialist. |
| **Coverage Duration** | Initial approval - 3 months. Recertifications - 1 year. |
| **Other Criteria** | For its FDA approved indications, there must be a diagnosis made by gas chromatography-mass spectrometry analysis of the urine with a positive identification of elevated bile acids. In addition, liver function tests must identify elevated serum aminotransferases with normal serum gamma glutamyltransferase. The initial approval will be for three months. After the initial three-month authorization, approval will be granted in one-year increments with documentation of improved liver function via aminotransferase lowering. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CIMZIA

## Products Affected

- Cimzia
- Cimzia Powder for Reconst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Cimzia will be covered for a diagnosis of ankylosing spondylitis in patients with documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Cyltezo, Hadlima, Xeljanz/XR. Covered for a diagnosis of moderate to severe active Crohn's disease in patients with a documented failure of two of the following: Humira, Cyltezo, Hadlima, Rinvoq, Skyrizi, Stelara. Covered for the diagnosis of non-radiographic axial spondyloarthritis. Covered for a diagnosis of moderate to severe rheumatoid arthritis in patients with documented failure to two of the following alternatives: Enbrel, Humira, Cyltezo, Hadlima, Orencia, Rinvoq, Xeljanz/XR. Covered for the diagnosis of moderate to severe plaque psoriasis that involves at least 5% body surface area (BSA). Covered for the diagnosis of moderate to severe plaque psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. In addition, there must be documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Cyltezo, Hadlima, Otezla, Skyrizi, Stelara. Covered for a diagnosis of psoriatic arthritis in patients with documented failure of two of the following alternatives: Cosentyx, Enbrel, Humira, Cyltezo, Hadlima, Otezla, Orencia, Rinvoq, Stelara, Xeljanz/XR. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements |

**Prior Authorization Requirements**
**Effective September 1, 2024**

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COSENTYX

## Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous syringe 75 mg/0.5 mL
- Cosentyx UnoReady Pen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist or rheumatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of ankylosing spondylitis in patients with refractory disease defined by failure of at least one NSAID at maximally tolerated dose taken for a minimum one-month duration. Covered for the diagnosis of moderate to severe chronic plaque psoriasis with psoriasis that involves at least 5% body surface area (BSA). Covered for the diagnosis of moderate to severe chronic plaque psoriasis in patients with psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patients also must meet one of the following criteria: 1) had a 3-month trial of acitretin, methotrexate, or cyclosporine therapy resulting in intolerance or clinical failure or 2) have tried UVB/coal tar or PUVA/topical corticosteroids for at least 3 months or 3) have tried and failed at least two of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for a diagnosis of psoriatic arthritis. Covered for a diagnosis of non-radiographic axial spondyloarthritis. Covered for a diagnosis of moderate to severe hidradenitis suppurativa (HS). Covered for patients with a diagnosis of enthesitis-related arthritis who have failed to respond to and/or are intolerant to at least one month of maximally tolerated NSAID therapy. Requests for non-FDA approved |

| PA Criteria | Criteria Details |
|---|---|
| | indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CUVRIOR

## Products Affected

- Cuvrior

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of stable Wilson's disease who are de-coppered and tolerant to penicillamine. Must have contraindication to penicillamine tablets (generic for Depen) and contraindication to trientine capsules (generic for Syprine). Recertification requires evidence of provider re-evaluation showing that patient cannot be transitioned to maintenance on penicillamine tablets (generic for Depen) or trientine capsules (generic for Syprine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CYLTEZO

## Products Affected

- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV
- Cyltezo(CF) subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.4 mL, 40 mg/0.8 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) for pts w/ refractory disease defined by failure of at least one NSAID at maximally tolerated dose for at least 1 month. Covered for moderate to severe active CROHN'S DISEASE. In addition, the patient must meet ONE of the following criteria: 1) patient continues to experience disease flare despite at least 4 weeks of maximally tolerated budesonide, up to 9mg/day (or equivalent therapeutic glucocorticoid), 2) treatment with an immunomodulator (such as azathioprine or 6-mp) fails to maintain remission in a case of steroid dependent or steroid refractory disease, 3) documentation is provided that azathioprine, 6-mp, or MTX is not effective, contraindicated, or not tolerated. Covered for moderate to severe HIDRADENITIS SUPPURATIVA. Covered for moderate to severely active JUVENILE IDIOPATHIC ARTHRITIS (JIA). Pt must have failed to respond to or are intolerant to approved DMARD agents, such as MTX, NSAIDS, analgesics or corticosteroids, either alone or in combination. Covered for moderate to severe chronic PLAQUE PSORIASIS that involves at least 5% of their body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patient also |

| PA Criteria | Criteria Details |
|---|---|
| | must meet one of the following criteria (requirement bypassed if patient has tried UVB and coal tar or PUVA and topical corticosteroids--a non-part- d service): 1) had a 3-month trial of acitretin, methotrexate (MTX), or cyclosporine therapy resulting in intolerance or clinical failure OR 2) have tried and failed at least TWO of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for PSORIATIC ARTHRITIS (PsA). Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as MTX, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in pts with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. Covered for non-infectious intermediate, posterior uveitis and panuveitis in pts with an ineffective response, contraindication, or intolerance to TWO of the following regimens: 1) topical or injected ophthalmologic steroid, 2) oral systemic steroid, 3) immunosuppressive agent, such as azathioprine, mycophenolate, or MTX. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DAYBUE

## Products Affected

- Daybue

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic/lab test results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or provider who specializes in the treatment of Rett Syndrome (RTT) |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Covered for patients with a diagnosis of classic or typical Rett Syndrome (RTT) and have a confirmed mutation of the MECP2 gene. Recertification will require subjective or objective evidence from provider that the patient is tolerating therapy and the drug is providing ongoing benefit in terms of disease improvement or stability (i.e., symptoms, quality of life measures, and/or functional measures). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DICLOFENAC 3% TOPICAL GEL

## Products Affected

- diclofenac sodium topical gel 3 %

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Diclofenac 3% gel will be covered for the diagnosis of actinic keratoses. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DICLOFENAC PATCH

## Products Affected

- diclofenac epolamine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Three months |
| **Other Criteria** | Diclofenac patch will be covered for the treatment of acute pain due to minor strains, sprains, and contusions. Acute pain is defined as short-term pain not lasting longer than a three-month period. Chronic pain is defined as a condition that requires pain management that exceeds a three-month period, such as rheumatoid arthritis, osteoarthritis, and peripheral neuropathy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DIHYDROERGOTAMINE

## Products Affected

- dihydroergotamine nasal

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Excluded for prevention of migraines or cluster headaches. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a headache or pain specialist or neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the acute treatment of migraine headache in patients with documented trial and failure or severe intolerance to two different generic triptans (any dosage form) used in combination with a non-opioid analgesic (such as aspirin, NSAID, or acetaminophen). Will not be approved for prophylactic therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DOJOLVI

## Products Affected

- Dojolvi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, via appropriate molecular genetic testing confirming at least one known LC-FAOD mutation such as CPT1A, CPT2, ACADVL, HADHA, or HADHB. If molecular genetic testing is not definitive, then biochemical analysis showing diminished enzyme activity measured on skin fibroblasts must be provided. In addition to one of the above, plasma or dried blood spot acylcarnitine analysis showing a characteristic pattern consistent with LC-FAOD must be provided. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a metabolic disease specialist knowledgeable in disease-related dietary management. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of one of the following long-chain fatty acid oxidation disorders (LC-FAOD): very long chain acyl-CoA dehydrogenase (VLCAD) deficiency, carnitine palmitoyl transferase (CPT I OR CPT II) deficiency, long-chain 3-hydroxy-acyl-CoA dehydrogenase (LCHAD) deficiency, trifunctional protein (TFP) deficiency, or carnitine-acylcarnitine translocase (CACT) deficiency. The use of any other medium-chain-triglyceride (MCT) product should be discontinued before starting Dojolvi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DOPTELET

## Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. While no specific lab/diagnostic tests required, providing the results used to diagnose the condition is recommended, thereby reducing the likelihood that additional information will be needed to process the request. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist, gastroenterologist, hepatologist, or surgeon. |
| **Coverage Duration** | One month for chronic liver disease-associated thrombocytopenia. Two years for chronic ITP. |
| **Other Criteria** | Covered for a diagnosis of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure. For this diagnosis, platelet count must be less than 50,000 platelets per microliter. Covered for a diagnosis of chronic immune thrombocytopenia purpura (ITP) in patients who have experienced an insufficient response to previous treatment with either corticosteroids or immunoglobulins (IVIG). Insufficient response is defined as a platelet count of less than 30,000/microliter or greater than 30,000/microliter but with bleeding symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DOXEPIN TOPICAL CREAM

## Products Affected

- doxepin topical

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Doxepin topical cream will be covered for the treatment of short-term management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DRONABINOL

## Products Affected

- dronabinol

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Anorexia due to AIDS - 1 yr. Chemo-induced nausea/vomiting-6 mos. Post-op nausea/vomiting-1 month. |
| **Other Criteria** | For the prophylaxis of nausea and vomiting associated with cancer chemotherapy or for the prophylaxis of post-operative nausea and vomiting, there must be a documented failure of one 5HT-3 receptor antagonist. There are no additional requirements for patients with AIDS-associated loss of appetite. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DROXIDOPA

## Products Affected

- droxidopa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DUPIXENT

## Products Affected

- Dupixent Pen subcutaneous pen injector 200 mg/1.14 mL, 300 mg/2 mL
- Dupixent Syringe subcutaneous syringe 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. For MODERATE-TO-SEVERE EOSINOPHILIC ASTHMA: (1) either a) submission of blood eosinophil count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or b) documentation asthma requires daily oral corticosteroid for control and (2) adult pts with pre-bronchodilator FEV1 less than 80% predicted and (3) experienced inadequate control of asthma sxs or severe intolerance with both Fasenra and Nucala. For MODERATE TO SEVERE ATOPIC DERMATITIS: documentation of a trial of 2 of the following 3 options during the 6 mos preceding request: a) tx w/ high-potency topical steroid for minimum 14-day duration or tx w/ a medium-potency topical steroid for a min. 28-day duration, b) tx w/ topical tacrolimus, c) tx w/ an oral or injectable immunosuppressant, such as a corticosteroid indicated or compendia supported for tx of AD. For CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: (1) documentation of inadequate response to 3-month trial of Xhance nasal spray and inadequate response with Nucala and (2) trial with oral steroids in past 6 months or prior sinus surgery in past 2 years. For EOSINOPHILIC ESOPHAGITIS: (1) diagnosis confirmed by upper endoscopy w/ biopsy and (2) clinical sxs such as difficulty swallowing, food impaction (getting stuck in the esophagus), acid reflux, n/v, abdominal or chest pain), and (3) provider must attest that other causes have been ruled out (including, but not limited to: GERD, HES, EGPA) and (4) documentation of serious side effects or drug failure with the following compendia-supported standard of care treatments: topical steroids (such as swallowed fluticasone or budesonide) with a PPI at twice daily dosing for at least 8 wks. For PRURIGO NODULARIS: (1) pruritis lasting at least 6 weeks (2) signs of repeated scratching, picking, or rubbing (i.e., excoriations and scars), (3) presence of multiple pruriginous firm, nodular lesions and (4) a history of failing at least a 2-week course of high-to-super-high-potency topical steroid. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |

**Prior Authorization Requirements**
**Effective September 1, 2024**

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by an allergist, gastroenterologist, immunologist, otolaryngologist, pulmonologist or dermatologist |
| **Coverage Duration** | Atopic dermatitis: 1 yr. All other diagnoses: initial - 6 months, recert every 1 year thereafter |
| **Other Criteria** | For ASTHMA: Dupixent must be used as add-on tx to existing maintenance tx. For ATOPIC DERMATITIS: must involve at least 10% body surface area prior to initial therapy. For CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: recertification will require documentation of continued use of intranasal corticosteroid and clinical benefit from Dupixent use (e.g., reduced polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal sxs, improved sense of smell). For EOSINOPHILIC ESOPHAGITIS: the diagnosis confirmed by upper endoscopy w/ esophageal biopsy must show at least 15 eosinophils per high-power field (or 60 eos/mm2). A positive response may include symptom resolution (an improvement in swallowing, decreased reflux, decreased food impaction) or other subjective or objective evidence from provider that use of Dupixent has improved the patient's condition. For PRURIGO NODULARIS: recertification requires a reduction in symptoms (pruritis) and clearer skin (less firm nodular lesions) from baseline/initial request. RECERTIFICATION for all indications requires some objective or subjective evidence of a positive response to treatment. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EGRIFTA

## Products Affected

- Egrifta SV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis, current medications (required that patient be currently on antiretroviral therapy). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EMFLAZA

## Products Affected

- deflazacort oral suspension
- deflazacort oral tablet 18 mg, 30 mg, 36 mg, 6 mg
- Emflaza oral suspension
- Emflaza oral tablet 18 mg, 30 mg, 36 mg, 6 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies for stated diagnosis, results of Duchenne Muscular Dystrophy (DMD) gene mutation study |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for all FDA approved indications with required documentation of significant side effects resulting from a minimum 3-month trial of oral prednisone. Examples of significant prednisone side effects include cushingoid appearance, central (truncal) obesity, undesirable weight gain, inability to manage diabetes or hypertension, steroid-induced mania, or sepsis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENBREL

## Products Affected

- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ankylosing spondylitis (AS) in pts with refractory disease defined by failure of at least one NSAID at maximally tolerated dose for at least 1 month. Covered for moderate to severely active juvenile idiopathic arthritis (JIA) in patients at least 2 years old. Patient must have failed to respond to and/or is intolerant to approved DMARD agents, such as methotrexate, NSAIDS, analgesics or corticosteroids, either alone or in combination. Covered for moderate to severe chronic plaque psoriasis that involves at least 5% body surface area. Covered for moderate to severe chronic plaque psoriasis in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patient also must meet one of the following criteria (requirement bypassed if pt has tried UVB and coal tar or PUVA and topical corticosteroids--a non-part-d service): 1) had a 3-month trial of acitretin, methotrexate, or cyclosporine therapy resulting in intolerance or clinical failure, OR 2) have tried and failed at least 2 of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered psoriatic arthritis (PsA). Covered for active moderate to severe rheumatoid arthritis (RA) in pts who have failed to respond to or are intolerant to one approved disease-modifying anti-rheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or |

| PA Criteria | Criteria Details |
|---|---|
| | hydroxychloroquine, either alone or in combination for a 3-month period. Requests will also be evaluated for off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENDARI

## Products Affected

- Endari

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for symptomatic pain relief of sickle cell disease. In addition, patient must have experienced inadequate pain relief with a minimum three-month trial or a hematologic toxicity reaction with hydroxyurea monotherapy. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENSPRYNG

## Products Affected

- Enspryng

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by a positive anti-aquaporin-4 (AQP4) antibody test (results must be provided). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an ophthalmologist or neurologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of Neuromyelitis Optica spectrum disorder (NMOSD) confirmed by a positive anti-aquaporin-4 (AQP4) antibody test. Patient must have had at least 2 Neuromyelitis Optica relapses in the last 24 months, one of which being within the last 12 months. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EPIDIOLEX

## Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERLEADA

## Products Affected

- Erleada oral tablet 240 mg, 60 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or hematologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of nonmetastatic, castration-resistant prostate cancer in patients with documentation of contraindication or had serious side effects to Nubeqa and Xtandi. Covered for a diagnosis of metastatic castration-sensitive prostate cancer in patients with documentation of contraindication or serious side effects to abiraterone and either Xtandi or Nubeqa. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ESRD

## Products Affected

- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL
- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, dialysis status (only if diagnosis of end-stage renal disease) |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EVENITY

## Products Affected

- Evenity subcutaneous syringe 210mg/2.34mL ( 105mg/1.17mLx2)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, DEXA scan report(s), previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year (refer to other criteria section) |
| **Other Criteria** | Covered for post-menopausal women at high risk for fracture. The patient must be considered high risk for fracture, which is defined as 1) history of previous osteoporosis-related fracture, 2) T- score of -2.5 SD or less, 3) T-score between -1.0 and -2.5 SD below normal and a FRAX score for hip fracture of 3% or greater or the risk for other bone fracture is 20% or greater. Patient must also have experienced therapeutic failure, severe intolerance or a contraindication to an oral bisphosphonate or be an inappropriate candidate for oral bisphosphonate therapy based on clinical presentation. Therapeutic failure is defined as a decrease in bone mineral density or a fracture while on bisphosphonate therapy. Severe intolerance defined as chest pain, difficulty swallowing, intense abdominal pain or chronic dyspepsia when oral bisphosphonate therapy was taken according to manufacturer recommendations. Oral bisphosphonates may be clinically inappropriate for a patient that is bedridden/unable to sit upright for 30 minutes unsupervised or has esophageal ulcerations, esophageal stricture, Barrett's Esophagitis, or active ulcers. Additionally, patient must have documented severe intolerance or contraindication to generic teriparatide. The FDA approved labeling does not recommend duration to exceed more than 12 monthly doses. Request will also be evaluated for part b versus part |

| PA Criteria | Criteria Details |
|---|---|
| | d coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EVRYSDI

## Products Affected

- Evrysdi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of Type I, II, or III Spinal Muscular Atrophy confirmed by targeted mutation analysis showing homozygous deletions of SMN1 gene or homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) or compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1). Patient must have genetic testing confirming 1, 2, 3, or 4 copies of the SMN2 gene. Additionally, progress notes containing results of at least one of the following baseline motor function exams must be provided: a) Hammersmith Infant Neurological exam (HINE) or b) Hammersmith Functional Motor Scale Expanded (HFMSE) or c) Upper Limb Module (ULM) test/Revised Upper Limb Module test (RULM) or d) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) or e) Motor Function Measure 32 (MFM32) or f) Bayley Scales of Infant and Toddler Development- Third Edition gross motor scale (BSID-III) (for infantile-onset disease only). Recertification will require documentation of objective improvement of motor function relative to baseline as measured by retest of pretreatment exam. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FASENRA

## Products Affected

- Fasenra Pen
- Fasenra subcutaneous syringe 10 mg/0.5 mL, 30 mg/mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling and Fasenra will not be covered for the treatment of other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic test results to confirm the diagnosis of eosinophilic asthma (such as blood eosinophil count, pulmonary function tests, or other tests performed to confirm the diagnosis), and documentation of previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an allergist, immunologist, or pulmonologist |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for the treatment of severe persistent asthma with an eosinophilic phenotype. For a patient not dependent on oral steroids, the patient must have a peripheral blood eosinophil count of at least 300 cells per microliter within the preceding 6 weeks before the Fasenra request. For a patient dependent on oral steroids, the patient must have a peripheral blood eosinophil count of at least 150 cells per microliter within the preceding 6 weeks before Fasenra request. For adults, patient must have a pre-bronchodilator forced expiratory volume in 1 second (FEV1) of less than 80% of the predicted value. For patients under 18 years old, patient must have a pre-bronchodilator FEV1 of less than 90% of the predicted value or a ratio of the FEV1 to the forced vital capacity (FVC) of less than 0.8. The patient must be maintained on asthma treatment consistent with the GINA or NHLBI guidelines, which recommend the combination of a high-dose inhaled steroid with a long-acting beta agonist (preferred by GINA guidelines), or leukotriene inhibitor, or long-acting muscarinic antagonist, or theophylline. If the above criteria are met, coverage will be provided if the patient experienced 2 or more asthma exacerbations (defined as unscheduled doctor visits, urgent care visits, emergency room visits, |

| PA Criteria | Criteria Details |
|---|---|
| | hospital admissions, or documented need for acute systemic steroids) within the preceding 12 months. Initial approval will be for 6 months. Upon recertification, documentation should be provided validating reduction in asthma exacerbations as defined above. Requests will also be evaluated for part B vs part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FILSPARI

## Products Affected

- Filspari oral tablet 200 mg, 400 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a nephrologist or provider specializing in IgA nephropathy. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered to reduce proteinuria in patients with a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy. Patient must have an eGFR greater than 35mL/min/1.73m2 and have proteinuria (defined as greater than or equal to 1 g/day OR a urine protein creatinine ratio (UPCR) greater than or equal to 1.5 g/g). In addition, the patient must have received the maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a minimum of 3 months prior to starting Filspari, unless the patient is unable to tolerate or has a contraindication to an ACEi or ARB. Recertification will require documentation of an eGFR of at least 30 mL/min/1.73 m2 AND either a reduction in total urine protein from baseline OR a reduction in UPCR from baseline. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FINTEPLA

## Products Affected

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FIRDAPSE

## Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic test results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or neuromuscular specialist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of Lambert-Eaton Myasthenic Syndrome that has been confirmed by electromyography or calcium channel antibody testing. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GALAFOLD

## Products Affected

- Galafold

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded in combination with Fabrazyme (agalsidase beta). Excluded for patients with a glomerular filtration rate (GFR) less than 30 mL/min. |
| **Required Medical Information** | In male patients, diagnosis confirmed by either an enzyme assay test (in leukocytes, plasma, fibroblasts or dried blood spots) demonstrating complete deficiency or less than 3% of normal of alpha-glactosidase a (GLA) activity, or documented GLA gene mutation by gene sequencing. For female patients, documentation must be confirmed by documented GLA mutation by gene mutation. Indicate current therapies for the treatment of Fabry disease. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a nephrologist, a genetic specialist, or prescriber experienced in the management of Fabry disease |
| **Coverage Duration** | Initial approval - 1 year. Recertifications - 2 years. |
| **Other Criteria** | Covered for a confirmed diagnosis of Fabry disease. In addition, male and female patients must have an amenable gene mutation based on the human embryonic kidney (HEK) 293 assay (refer to manufacturer prescribing information for the listing of amenable GLA variants). The patient must also have at least one of the following documented symptoms or physical findings of Fabry disease: angiokeratomas (characteristic lysosomal disease skin rashes), hypohidrosis (decreased sweating), acroparesthesia (neuropathic pain in the hands and feet), cornea verticillata and characteristic corneal /lenticular opacities, diarrhea, abdominal pain, nausea, vomiting, flank pain, heat/cold intolerance, vertigo, tinnitus, diplopia, fatigue , cardiac disease (including hypertrophic cardiomyopathy), arrhythmias, progressing renal disease (proteinuria to end stage renal disease), and stroke. Male patients with complete deficiency or less than 3% of normal alpha-Galactosidase A activity are not required to have one of the symptoms or physical findings above. Requests for recertification will require documentation that supports a positive response to therapy for symptomatic individuals. Requests for non-FDA |

| PA Criteria | Criteria Details |
|---|---|
| | approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GATTEX

## Products Affected

- Gattex 30-Vial

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis and evidence of dependency on parenteral nutrition support. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GLP-1 AGONISTS

## Products Affected

- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 1 mg/dose (4 mg/3 mL), 2 mg/dose (8 mg/3 mL)
- Rybelsus
- Trulicity
- Victoza 3-Pak

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for weight management and as limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of type 2 diabetes mellitus. Excluded for use in weight management. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GONADOTROPIN RELEASING HORMONE ANALOGS

## Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- leuprolide (3 month)
- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped (3 month) intramuscular syringe kit 11.25 mg
- Lupron Depot-Ped intramuscular kit 7.5 mg (Ped)
- Lupron Depot-Ped intramuscular syringe kit
- Trelstar intramuscular suspension for reconstitution

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months for endometriosis. One year for all other diagnoses. |
| **Other Criteria** | Lupron/leuprolide is covered for management of endometriosis, including pain relief and reduction of endometriotic lesions. Authorization will be for up to 6 months, because of a lack of safety data with long term use and concerns regarding effects on bone density. Lupron/leuprolide is covered for treatment of advanced prostate cancer, defined as stage III or stage IV. Lupron/leuprolide is covered for treatment of precocious puberty. Lupron/leuprolide is covered as adjunct therapy for preoperative hematologic improvements of patients with anemia (hematocrit less than or equal to 30% and or hemoglobin less than or equal to 10.2 g/dL) caused by uterine leiomyomata. Trelstar is covered for treatment of advanced prostate cancer. Requests will also be evaluated for off-label use. |

**Prior Authorization Requirements**
**Effective September 1, 2024**

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GRALISE

## Products Affected

- gabapentin oral tablet extended release 24 hr 300 mg, 600 mg
- Gralise oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | For the treatment of post-herpetic neuralgia, there must be documentation of severe intolerance or clinical failure to generic immediate release gabapentin. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GROWTH HORMONE

## Products Affected

- Genotropin
- Genotropin MiniQuick
- Humatrope injection cartridge
- Norditropin FlexPro
- Nutropin AQ Nuspin
- Omnitrope
- Serostim subcutaneous recon soln 4 mg, 5 mg, 6 mg
- Zomacton

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | When used to increase height, growth hormone therapy will not be covered in pediatric patients with closed epiphyses. |
| **Required Medical Information** | General-growth charts, height/weight, height velocity. Somatotropin deficiency in children requires documentation of diminished growth hormone response (max peak less than 10ng/mL) to 2 or more different provocation tests (such as levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon) or documentation of low IGF-1 or IGFBP3 for age, sex, and pubertal status in children age 6 or greater in the absence of chronic disease along with a height velocity less than 25th percentile in the 6-12 months prior to growth hormone therapy. In addition to one of the above findings there must also be documentation of two of the following: 1) growth velocity less than 7cm/yr before age three 2) bone age at least 2 SD below normal for chronological age 3) a known risk factor for growth hormone deficiency (such as congenital hypopituitarism, panhypopituitarism, or prior brain radiation). Somatotropin deficiency in adults requires documentation of negative response to provocative test with max peak of 5ng/mL along with documentation of clinical symptoms such as increased weight and body fat mass, decreased lean body mass, decreased exercise tolerance, decreased muscle mass and strength, reduced cardiac performance, reduced bone density, poor sleep, impaired sense of well-being or lack of motivation. Alternatively, will accept insulin tolerance test with max peak less than 5ng/mL (unless contraindicated in which case will accept IV arginine in combination with GH-releasing hormone with max peak less than 10ng/mL.) If there is documentation of deficiency of 3 or more pituitary hormones, ITT or arginine tests are not required. Recertification- in children requires the following every 12 months: current growth velocity, growth charts (height and weight), current bone age, puberty status, and radiographic testing to determine if epiphyses are closed at age 14 in girls and age 16 in boys. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist, pediatric endocrinologist, nephrologist, infectious disease specialist, or gastroenterologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Children-covered for treatment of short stature in Turner Syndrome. Covered for children with height less than 3rd percentile for chronological age with renal insufficiency defined as serum creatinine greater than 3.0 mg/dL or creatinine clearance of 5-75 mL/min per 1.73m3 before renal transplant. Covered for Prader-Willi syndrome with short stature or growth failure. Covered for children with intrauterine growth failure or small for gestational age who do not catch up by 2 years of age. Covered for Noonan Syndrome with short stature (when height is at least 2 SD below normal. Covered for children with SHOX deficiency demonstrated by chromosome analysis and whose epiphyses are not closed. Adults and children- growth hormone therapy is covered for a diagnosis of somatotropin deficiency (see required medical info). Covered for AIDS wasting or cachexia or children with HIV associated failure to thrive defined as a greater than 10% of baseline weight loss or weight less than 90% of ideal body weight and either chronic diarrhea or chronic weakness not otherwise explained. Covered for patients with short bowel syndrome who are experiencing malabsorption, malnutrition, weight loss or dehydration despite specialized nutritional support. Note- Omnitrope must be used when the diagnosis is growth hormone deficiency, Prader-Willi syndrome or small for gestational age except in the following situations: Humatrope or Genotropin will be authorized only when the patient has a documented sensitivity to both benzyl alcohol (in Omnitrope 5 pen and vials) and phenol (in Omnitrope 10 pen). If a patient has a sensitivity just one of these agents, then the alternative Omnitrope product must be used. If the patient is age 3 and under, then Omnitrope 10 pen should be used as benzyl alcohol should be avoided in this population |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HADLIMA

## Products Affected

- Hadlima
- Hadlima PushTouch
- Hadlima(CF)
- Hadlima(CF) PushTouch

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) for pts w/ refractory disease defined by failure of at least one NSAID at maximally tolerated dose for at least 1 month. Covered for moderate to severe active CROHN'S DISEASE. In addition, the patient must meet ONE of the following criteria: 1) patient continues to experience disease flare despite at least 4 weeks of maximally tolerated budesonide, up to 9mg/day (or equivalent therapeutic glucocorticoid), 2) treatment with an immunomodulator (such as azathioprine or 6-mp) fails to maintain remission in a case of steroid dependent or steroid refractory disease, 3) documentation is provided that azathioprine, 6-mp, or MTX is not effective, contraindicated, or not tolerated. Covered for moderate to severe HIDRADENITIS SUPPURATIVA. Covered for moderate to severely active JUVENILE IDIOPATHIC ARTHRITIS (JIA). Pt must have failed to respond to or are intolerant to approved DMARD agents, such as MTX, NSAIDS, analgesics or corticosteroids, either alone or in combination. Covered for moderate to severe chronic PLAQUE PSORIASIS that involves at least 5% of their body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patient also must meet one of the following criteria (requirement bypassed if patient |

| PA Criteria | Criteria Details |
|---|---|
| | has tried UVB and coal tar or PUVA and topical corticosteroids--a non-part- d service): 1) had a 3-month trial of acitretin, methotrexate (MTX), or cyclosporine therapy resulting in intolerance or clinical failure OR 2) have tried and failed at least TWO of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for PSORIATIC ARTHRITIS (PsA). Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as MTX, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in pts with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. Covered for non-infectious intermediate, posterior uveitis and panuveitis in pts with an ineffective response, contraindication, or intolerance to TWO of the following regimens: 1) topical or injected ophthalmologic steroid, 2) oral systemic steroid, 3) immunosuppressive agent, such as azathioprine, mycophenolate, or MTX. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HETLIOZ

## Products Affected

- Hetlioz
- Hetlioz LQ
- tasimelteon

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Hetlioz LQ suspension will not be approved for non-24-hour sleep-wake disorder. |
| **Required Medical Information** | Diagnosis, including supporting lab/diagnostic test results (such as urinary melatonin and/or cortisol levels or actigraphy over a several week interval). For Smith-Magenis Syndrome (SMS), appropriate genetic testing is also required. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a sleep specialist or neurologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Hetlioz/tasimelteon capsules will be covered for a diagnosis of non-24-hour sleep-wake disorder for blind individuals who lack light perception. Based on the patient population used in clinical studies evaluating the efficacy of Hetlioz, Hetlioz/tasimelteon capsules will only be approved in patients with non-24 who are totally blind. Hetlioz LQ suspension will not be approved for non-24-hour sleep-wake disorder. Hetlioz LQ suspension and Hetlioz/tasimelteon capsules will be covered for nighttime sleep disturbances in Smith-Magenis syndrome (SMS). For SMS, patients must provide genetic testing confirmation of chromosome 17p11.2 deletion or RAI1 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HORIZANT

## Products Affected

- Horizant oral tablet extended release 300 mg, 600 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | For the treatment of post-herpetic neuralgia, there must be documentation of severe intolerance or clinical failure of generic gabapentin. For the treatment of restless legs syndrome, there must be documentation of severe intolerance or clinical failure of immediate release ropinirole. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HUMIRA

## Products Affected

- Humira (ONLY NDCS STARTING WITH 00074) subcutaneous syringe kit 40 mg/0.8 mL
- Humira Pen (ONLY NDCS STARTING WITH 00074)
- Humira(CF) (ONLY NDCS STARTING WITH 00074) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL
- Humira(CF) Pen (ONLY NDCS STARTING WITH 00074) subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) Pen Crohns-UC-HS (ONLY NDCS STARTING WITH 00074)
- Humira(CF) Pen Pediatric UC (ONLY NDCS STARTING WITH 00074)
- Humira(CF) Pen Psor-Uv-Adol HS (ONLY NDCS STARTING WITH 00074)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) for pts w/ refractory disease defined by failure of at least one NSAID at maximally tolerated dose for at least 1 month. Covered for moderate to severe active CROHN'S DISEASE. In addition, the patient must meet ONE of the following criteria: 1) patient continues to experience disease flare despite at least 4 weeks of maximally tolerated budesonide, up to 9mg/day (or equivalent therapeutic glucocorticoid), 2) treatment with an immunomodulator (such as azathioprine or 6-mp) fails to maintain remission in a case of steroid dependent or steroid refractory disease, 3) documentation is provided that azathioprine, 6-mp, or MTX is not effective, contraindicated, or not tolerated. Covered for moderate to severe HIDRADENITIS SUPPURATIVA. Covered for moderate to severely active JUVENILE IDIOPATHIC ARTHRITIS (JIA). Pt must have failed to respond to or are intolerant to approved DMARD agents, such as MTX, NSAIDS, analgesics |

| PA Criteria | Criteria Details |
|---|---|
| | or corticosteroids, either alone or in combination. Covered for moderate to severe chronic PLAQUE PSORIASIS that involves at least 5% of their body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patient also must meet one of the following criteria (requirement bypassed if patient has tried UVB and coal tar or PUVA and topical corticosteroids--a non-part- d service): 1) had a 3-month trial of acitretin, methotrexate (MTX), or cyclosporine therapy resulting in intolerance or clinical failure OR 2) have tried and failed at least TWO of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for PSORIATIC ARTHRITIS (PsA). Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as MTX, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in pts with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. Covered for non-infectious intermediate, posterior uveitis and panuveitis in pts with an ineffective response, contraindication, or intolerance to TWO of the following regimens: 1) topical or injected ophthalmologic steroid, 2) oral systemic steroid, 3) immunosuppressive agent, such as azathioprine, mycophenolate, or MTX. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HYFTOR

## Products Affected

- Hyftor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist, neurologist, or geneticist. |
| **Coverage Duration** | Initial 3 months. Recertifications 6 months. |
| **Other Criteria** | Covered for treatment of facial angiofibroma associated with tuberous sclerosis. Patient must have three or more angiofibroma papules at baseline (each at least 2 mm in diameter and with redness) on the face. Initial recertification requires provider documentation of objective and/or subjective evidence of reduced angiofibroma size and/or redness resulting from use of Hyftor. Subsequent recertifications require providers objective and/or subjective evidence that use of Hyftor has provided patient with continued stability or further improvement from status noted at initial recertification. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ILUMYA

## Products Affected

- Ilumya

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of moderate to severe plaque psoriasis that involves at least 5% body surface area (BSA). Covered for the diagnosis of moderate to severe plaque psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. In addition, there must be documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INCRELEX

## Products Affected

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Increlex will not be covered for growth promotion in patients with closed epiphyses or as a substitute for growth hormone replacement therapy. IV administration will not be covered. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results (such as IGF-1 levels and GH levels). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist, pediatric endocrinologist, or nephrologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Increlex will be covered in patients with severe primary IGF-1 deficiency defined as height SD score less than -3.0, basal IGF-1 SD score less than -3.0, and normal or elevated GH. They will also be covered in patients with growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH. Normal dose is 40-120mcg/kg sq twice daily given 20 minutes before or after a meal or snack to avoid hypoglycemia. Doses greater than 120mcg/kg will not be covered. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INGREZZA

## Products Affected

- Ingrezza Initiation Pk(tardiv)
- Ingrezza oral capsule 40 mg, 60 mg, 80 mg
- Ingrezza Sprinkle oral capsule, sprinkle 40 mg, 60 mg, 80 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or a psychiatrist |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ISTURISA

## Products Affected

- Isturisa oral tablet 1 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling and excluded for other forms of Cushing's Syndrome not Cushing's disease. |
| **Required Medical Information** | Diagnosis, mean urinary free cortisol (UFC) level measured over three 24-hour, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist. |
| **Coverage Duration** | Initial approval and increase in dose 3 months. Recertification of previously approved dose 1 year. |
| **Other Criteria** | Covered for a diagnosis of Cushing's disease in patients with documentation of clinical symptoms (such as diabetes, central obesity, moon face, buffalo hump, osteoporosis, muscle wasting, hypertension, depression, or anxiety) who have a mean urinary free cortisol (UFC) level that is at least 1.5x the upper limit of normal measured over three 24-hour measurements (ULN = 50 mcg/24 hours or 145 nmol/24 hours). Also, there must be documentation of a failed pituitary surgery or contraindication to pituitary surgery as well as serious side effects or drug failure with Signifor/pasireotide. A dose increase request will require both documentation to show UFC levels above the upper limit of normal on current dose and documentation that the patient is still experiencing Cushing's disease symptoms. All dose increases approved for 3 months. Recertification of the same dose will require both documentation of a recent UFC level within normal limits and documentation of improvement in the symptoms of Cushing's disease. Recertifications at same dose as previously approved are approved for 1 year. For all requests, the prescriber must make clear the dose they are planning to use. Recertification at a previously approved dose (maintenance dosing) will allow the dose requested only. Dose increases must be in accordance with FDA labeling and titrated by no greater than 1 mg or 2 mg twice daily, no more frequently than every 2 weeks based on the rate of cortisol changes, |

| PA Criteria | Criteria Details |
|---|---|
| | individual tolerability, and improvement in signs and symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IVIG

## Products Affected

- Bivigam
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked injection solution 1 gram/10 mL (10 %)
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C injection solution 1 gram/10 mL (10 %)
- Octagam
- Panzyga
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded under Part D if intravenous immune globulin (IVIG) is provided in the home for individual with diagnosis of primary immune deficiency disease. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Two years for chronic conditions. One month for acute conditions. 5 days for Guillain-Barre |
| **Other Criteria** | Requests will be evaluated for Part B vs Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# JOENJA

## Products Affected

- Joenja

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an immunologist, allergist, hematologist, or provider who specializes in the treatment of activated phosphoinositide 3-kinase delta syndrome (APDS) |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for a diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) in patients 12 years of age or older and who weigh at least 45 kg. Must have a confirmed APDS-associated genetic PI3K-delta mutation with a documented variant in either PIK3CD or PIK3R1 AND must meet at least one of the following: a. Have nodal and/or extranodal lymphoproliferation OR b. Have presence of at least 1 measurable nodal lesion on CT or MRI OR c. Have clinical findings and manifestations compatible with APDS (such as history of repeated oto-sino-pulmonary infections, organ dysfunction (i.e., lung, liver), bronchiectasis, cytopenias, gastrointestinal disease, immune dysregulation (i.e., decreased naive B cells, reversed CD4/CD8 ratio)). Recertification will require documentation that the patient has responded to therapy (i.e., improvement in clinical findings and/or manifestations of APDS such lymphoproliferation, recurrent infections, cytopenia, immunophenotyping) OR subjective evidence from provider that Joenja has improved patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# JUXTAPID

## Products Affected

- Juxtapid oral capsule 10 mg, 20 mg, 30 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, lab/diagnostic test results (must include baseline LDL level), current and previous therapies for stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a Cardiologist, Endocrinologist, or Lipidologist |
| **Coverage Duration** | Initial approval - 26 weeks. Recertifications - 1 year. |
| **Other Criteria** | Clinical diagnosis will be based on inclusion criteria for clinical trial: documented functional mutation in both LDL receptor alleles or skin fibroblast LDL receptor activity less than 20% of normal, or untreated total cholesterol more than 500 mg/dL and triglycerides less than 300 mg/dL and both parents with documented total cholesterol more than 250 mg/dL. Baseline LDL must be greater than 130 despite use of the following combination of moderate dose (atorvastatin 40 or equivalent) high-potency statin (atorvastatin, rosuvastatin, pitavastatin, simvastatin) with another lipid lowering agent. For patients with a contraindication or intolerance to statin therapy, the use of other lipid lowering agents will meet this prerequisite requirement. Documentation of lack of response or severe intolerance to Repatha is required. Initial approval will be 26 weeks. Further approval will require evidence of improvement over baseline LDL level. If LDL level meets recertification requirements, then the request will be reviewed annually thereafter. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# JYNARQUE

## Products Affected

- Jynarque oral tablet 15 mg, 30 mg
- Jynarque oral tablets, sequential

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. While no specific lab/diagnostic tests required, providing the results used to diagnose the condition is recommended, thereby reducing the likelihood that additional information will be needed to process the request. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a nephrologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of autosomal dominant polycystic kidney disease (ADPKD). ADPKD must be rapidly progressing, as defined by either 1) confirmed GFR decline of at least 5 ml/min/1.73 m2 per year over 1 year and/or 2.5 ml/min/1.73 m2 per year over a period of 5 years or 2) total kidney volume increase of at least 5% per year confirmed by repeated ultrasound or MRI measurements taken at least 6 months apart. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | COVERAGE WILL BE EXCLUDED IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508 DEL MUTATION IN THE CFTR GENE. |
| **Required Medical Information** | Diagnosis, lab/diagnostic results to include testing for CFTR gene mutation that is responsive to ivacaftor |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KEVEYIS

## Products Affected

- Keveyis
- Ormalvi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or geneticist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KEVZARA

## Products Affected

- Kevzara

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a rheumatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of moderate to severe rheumatoid arthritis in patients with documented failure to two of the following alternatives: Enbrel, Humira, Orencia, Rinvoq, Xeljanz/XR. Covered for the diagnosis of polymyalgia rheumatica (PMR) in patients who have had an inadequate response to corticosteroids or who cannot tolerate a corticosteroid taper. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KINERET

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | For Rheumatoid Arthritis - 2 years. For all other diagnoses - 1 year. |
| **Other Criteria** | Covered for the treatment of moderate to severe rheumatoid arthritis for patients with documented failure to two of the following alternatives: Enbrel, Humira, Orencia, Rinvoq, Xeljanz/XR. Covered for the diagnosis of neonatal-onset multisystem inflammatory disease (NOMID). Covered for a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) in patients who have a confirmed mutation in the IL1RN gene. Recertification will require provider attestation that the patient has maintained a response to treatment. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KISQALI

## Products Affected

- Kisqali
- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or hematologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | When used as second line therapy or beyond for the diagnosis of advanced or metastatic breast cancer, documentation of severe intolerance or contraindication to Ibrance/palbociclib and Verzenio/abemaciclib will be required prior to approval of Kisqali/ribociclib. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KORLYM

## Products Affected

- Korlym
- mifepristone oral tablet 300 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded in patients who are pregnant, who have a history of unexplained vaginal bleeding/endometrial changes, who are currently receiving long-term corticosteroids, or who are currently on simvastatin, lovastatin or a medication that is a CYP3a substrate and has a narrow therapeutic range. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results (such as HbA1c levels and negative pregnancy test in women of childbearing age), and documentation of previous therapies (failure of surgery or not a candidate for surgery). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered in patients with a diagnosis of endogenous Cushing's syndrome and Type 2 diabetes or glucose intolerance. Patients must have failed surgery or not be a candidate for surgery. Women of childbearing age must have a negative pregnancy test prior to starting therapy and must not be nursing. Non-hormonal contraception must be used while on therapy, unless the patient has had a surgical sterilization, in which case, no additional contraception is needed. Hypokalemia should be corrected prior to treatment and monitored for during treatment. Patients should also be closely monitored for signs and symptoms of adrenal insufficiency. Recertification after one year will require the submission of patient progress notes and lab work that demonstrates clinical response or stabilization of disease. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# LIDOCAINE PATCH

## Products Affected

- lidocaine topical adhesive patch,medicated 5 %
- ZTlido

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LIVMARLI

## Products Affected

- Livmarli

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Note: LIVMARLI is not recommended and, therefore, will not be approved in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein. |
| **Required Medical Information** | Evidence of cholestasis (ONE of the following) must be provided: 1) total serum bile acid greater than the ULN for age, or 2) increased conjugated bilirubin levels or 3) otherwise unexplainable fat-soluble vitamin deficiency, or 4) gamma glutamyl transferase (GGT) greater than the ULN for age or 5) intractable pruritus explainable only by liver disease. Genetic testing confirming Alagille Syndrome (ALGS) or approved variant of progressive familial intrahepatic cholestasis (PFIC) is required. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by provider experienced with the management of Alagille syndrome (ALGS) or progressive familial intrahepatic cholestasis (PFIC). |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for treatment of cholestatic pruritus in patients with genetic testing confirmed Alagille syndrome (ALGS). Covered for treatment of cholestatic pruritus with progressive familial intrahepatic cholestasis (PFIC). For either indication, objective and/or subjective evidence of significant pruritus must be submitted by provider. Evidence of cholestasis must be provided (as described in required medical information). Recertification requires documentation of a decrease in pruritus from baseline and/or decrease in serum bile acid concentration from baseline. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# LUPKYNIS

## Products Affected

- Lupkynis

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, kidney biopsy results, baseline urine protein/creatinine ratio (UPCR) at time of request, baseline eGFR at time of request, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a rheumatologist or nephrologist |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for patients with a diagnosis of class III, IV, or V lupus nephritis (LN) confirmed by kidney biopsy. Patient must be established and continue on standard therapy with mycophenolate/MMF and corticosteroids. Lupkynis is not approved for use as monotherapy or with cyclophosphamide-based immunosuppressive therapy. Also, patient must have had previous trial and failure or severe intolerance with Benlysta/belimumab, used either for systemic lupus erythematosus (SLE) or LN. Recertification after initial 6-month approval requires reduction in UPCR from baseline and increase in eGFR from baseline. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MAVYRET

## Products Affected

- Mavyret oral pellets in packet
- Mavyret oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Mavyret will not be covered in patients with moderate or severe hepatic impairment (Child-Pugh B or C). Mayvret will not be covered for genotypes that are not supported by its FDA approved indication, compendia, or AASLD guidelines. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic test results including baseline HCV RNA results and HCV genotype, and documentation of current and previous therapies (if applicable). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or HCV/HIV specialist |
| **Coverage Duration** | 8 to 16 weeks (depending on diagnosis, FDA approved labeling, and AASLD/IDSA guidance) |
| **Other Criteria** | For off-label Mavyret reviews, criteria will be applied consistent with compendia and current AASLD/IDSA guidance. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# METFORMIN ER

## Products Affected

- metformin oral tablet extended release (osm) 24 hr
- metformin oral tablet,ER gast.retention 24 hr

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of Type-2 diabetes. Documentation of clinical failure or severe intolerance of both immediate-release metformin (generic equivalent of Glucophage) and extended-release metformin (generic equivalent of Glucophage XR) is required before the approval of metformin ER osmotic (generic Fortamet) or metformin ER gastric (generic Glumetza). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# METHAMPHETAMINE

## Products Affected

- methamphetamine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used for weight loss, even if non-cosmetic (such as morbid obesity). |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MIGLUSTAT

## Products Affected

- miglustat

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy of miglustat (Zavesca) and Cerezyme/Ceredase is excluded. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic test results (such as enzyme analysis, mutation analysis, bone marrow studies, or other tests performed to confirm the diagnosis) |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Miglustat is covered for Type 1 Gaucher Disease in patients for whom enzyme replacement therapy with Cerezyme is not a therapeutic option due to allergy, hypersensitivity, or poor venous access. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MIGRAINE OTHER

## Products Affected

- Nurtec ODT
- Ubrelvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a headache or pain specialist or neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | For the acute treatment of migraine headache with or without aura, Nurtec and Ubrelvy are covered with documentation of trial and failure or severe intolerance to one generic triptan product. For the prevention of episodic migraine, Nurtec requires previous trials with two different classes of medications, for at least eight weeks per trial, that are supported by compendia for the prophylactic treatment of migraine headache (such as amitriptyline, divalproex sodium, propranolol, topiramate, or venlafaxine) which resulted in intolerance or lack of clinical efficacy. For clinical failure due to intolerance, an eight-week trial of medication is not required. Recertification after initial approval will require documentation that the drug continues to effectively reduce frequency, duration, and severity of acute migraine headaches for the patient. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MOTPOLY XR

## Products Affected

- Motpoly XR oral capsule,extended release 24hr 100 mg, 150 mg, 200 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg. In addition, there must be documentation of severe intolerance, clinical failure, contraindication to or inability to take immediate release lacosamide. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MULPLETA

## Products Affected

- Mulpleta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. While no specific lab/diagnostic tests required, providing the results used to diagnose the condition is recommended, thereby reducing the likelihood that additional information will be needed to process the request. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist, gastroenterologist, hepatologist, or surgeon. |
| **Coverage Duration** | One month |
| **Other Criteria** | Covered for a diagnosis of thrombocytopenia defined as a platelet count of less than 50,000 platelets per microliter. In addition, the patient must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MYALEPT

## Products Affected

- Myalept

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of Myalept is excluded for the following conditions: metabolic disease not associated with congenital leptin deficiency, HIV-associated lipodystrophy |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. Diagnosis is confirmed through low serum leptin levels and the absence of subcutaneous fat. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MYTESI

## Products Affected

- Mytesi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Drug therapy will not be authorized for individuals who have a history of Ulcerative colitis, Crohn's disease, Celiac sprue, chronic pancreatitis, malabsorption, or any other GI disease associated with diarrhea. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the symptomatic relief of noninfectious diarrhea in individuals with HIV/AIDS on anti-retroviral therapy. In addition, documentation of clinical failure to either loperamide or diphenoxylate is required. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NAMZARIC

## Products Affected

- Namzaric oral cap,sprinkle,ER 24hr dose pack
- Namzaric oral capsule,sprinkle,ER 24hr

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Namzaric will be authorized for patients with a diagnosis of moderate to severe Alzheimer disease. There must also be documented stabilization on donepezil for a minimum of three months immediately preceding the request for Namzaric. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NAPROXEN ESOMEPRAZOLE

## Products Affected

- naproxen-esomeprazole

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and juvenile idiopathic arthritis in patients with a documented contraindication to the use of individual generic naproxen in combination with generic esomeprazole. Also, patient must have a trial with therapeutic failure or severe intolerance to a different combination of a generic NSAID (such as ibuprofen, celecoxib, meloxicam) with a generic proton pump inhibitor (such as omeprazole, pantoprazole, lansoprazole). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NITISINONE

## Products Affected

- nitisinone
- Nityr

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current therapies, pertinent lab/diagnostic test results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a physician specializing in the treatment of Tyrosinemia type 1 (such as a metabolic disease specialist). |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of hereditary tyrosinemia type 1. Patients must have the presence of succinylacetone (SSA) in the urine or blood / dried blood spots. Patients must have clinical features of tyrosinemia type 1, such as: failure to thrive, emesis, melena, hepatosplenomegaly, liver disease, cirrhosis, clotting abnormalities, renal disease/Fanconi syndrome, neurological crisis, rickets. Requests for Nityr tablets require documentation of severe intolerance or drug failure of the preferred product generic nitisinone capsules. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Nucala will not be covered for the relief of acute bronchospasm or status asthmaticus. Nucala will not be approved for granulomatosis with polyangiitis (also known as GPA or Wegeners granulomatosis) or microscopic polyangiitis. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic tests used to confirm diagnosis, current and previous therapies. For diagnosis of EGPA, baseline Birmingham vasculitis activity score (BVAS) from within 4 weeks prior to start of Nucala therapy must also be provided |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For asthma with eosinophilic phenotype, must be prescribed by an Allergist, Immunologist or Pulmonologist. For EGPA, must be prescribed by an Allergist, Immunologist, Pulmonologist, Neurologist, or Rheumatologist. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Cvrd sev prstnt asthma w/ EOS phenotype. Must have periph blood EOS ct at least 150 cells/mcl w/in past 6 wks before Nucala req or at least 300 cells/mcl in past yr. Adult pts must have pre-bronchodilator FEV1 less than 80%. Pts 6-18 yrs must have pre-bronchodilator FEV1 less than 90% or FEV1/FVC less than 0.8. Must be on asthma tx c/w GINA or NHLBI (combo high-dose ICS w/ LABA, LI, LAMA, or theoph). If above is met, cvrg will be provided if pt experienced 2 or more asthma exacerbations (e.g., unscheduled doctor/urgent care/ER visits, hospital admin, or need for acute systemic steroids) in past 12 mos. At recert, must validate reduction in asthma exacerbations as defined above. Cvrd tx adult pts with EGPA. Must have dx relapsing or refractory EGPA, existing for min past 6 mos. Pt must have 1 of the following: 1) hx of relapse requiring increase in cs dose, add or increase in other immunosuppressive tx, or hospitalization in past 2 yrs while on at least 7.5 mg/day prednisone (or equiv) within the past 6 mos or 2) must have failed to achieve remission following a std induction regimen administered for at least 3 mos or recurrence of sx of EGPA while |

| PA Criteria | Criteria Details |
|---|---|
| | tapering cs. Standard tx regimens may incl pred dosed at least 7.5 mg/day in combo w/ immunosuppressant (unless C/I). Must have hx or presence of asthma and blood EOS level at least 10% or an abs. EOS ct more than 1,000 cells/mcl w/in past 6 wks. Must be 2 or more of following: confirmation via biopsy, motor deficit or nerve conduction abnormality, pulm infiltrates, sinonasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura, or positive ANCA. Must be on stable dose oral cs (min 7.5mg/day of pred or equiv) for min 4 wks at Nucala req. At recert, must show sx remission while on Nucala. Remission defined as BVAS equal to zero while on max 7.5 mg/day dose pred or equiv. Cvrd for pts with min 6 mo hx HES w/ evidence EOS-mediated organ damage and/or dysfx where other causes for damage/dysfx have been excluded. Must have had 2 HES flares past 12 mos despite stable tx w/ oral steroids, immunosuppressive, or cytotoxic tx. HES flare defined as worsening of clinical s/sxs (e.g., derm, pulm, GI, cardiac, or neuro) or increasing EOS ct (measured on at least 2 occasions), resulting in need to incr. existing tx dose or addition of another tx. Cvrd dx active CRSwNP confirmed by direct exam, nasal endoscopy, imaging. Must have had inadequate response to at least a 3-month trial with Xhance NS. Must have trial with oral steroids in past 6 mos or prior sinonasal surgery in past 2 yrs. Nucala must be used as add-on tx w/ steroid NS. At recert, req cont'd use of steroid NS, clinical benefit from Nucala (e.g., reduced polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal sxs). Requests will be evaluated for Part BvD cvrg. Requests for non-FDA approved indications will be evaluated according to Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests will also be evaluated for off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUPLAZID

## Products Affected

- Nuplazid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Per the black box warning on Nuplazid, elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Therefore, Nuplazid will not be covered for elderly patients with dementia-related psychosis. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist, psychiatrist, or geriatrician |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUZYRA

## Products Affected

- Nuzyra oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | None |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist (outpatient only) |
| **Coverage Duration** | 14 days |
| **Other Criteria** | In the outpatient setting, Nuzyra is covered when prescribed in consultation with an Infectious Disease specialist. For patients discharged from an inpatient setting on Nuzyra therapy, the prescriber restriction is bypassed. Requests for non-FDA approved durations of therapy will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with complete biliary obstruction will be excluded from coverage. |
| **Required Medical Information** | Diagnosis, documentation of current and previous therapies for stated diagnosis, pertinent lab results (such as ALP levels, bilirubin, antimichondrial antibody/AMA test) |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a gastroenterologist or hepatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Ocaliva will be covered for the diagnosis of primary biliary cholangitis that has been confirmed by 2 of the following: positive antimitochondrial antibodies (AMA), history of increased alkaline phosphatase (ALP) levels, or liver biopsy consistent with primary biliary cholangitis. In addition, documentation must be provided that the patient is unable to tolerate ursodiol (ursodeoxycholic acid) or that the patient had an inadequate response to at least 12 months of ursodiol treatment. Inadequate response to ursodiol is defined as ALP greater than 1.67 times the upper limit of normal (ULN equals 118 u/L for females and 124 u/L for males) or total bilirubin level that is greater than 1 time the ULN, but less than 2 times upper limit of normal (ULN equals 1.1 mg/dL for females and 1.5 mg/dL for males). For patients who are unable to tolerate ursodiol, Ocaliva will be covered as monotherapy. For patients who had an inadequate response to ursodiol, Ocaliva will be covered when prescribed in combination with ursodiol. Upon recertification, there must be documentation of subjective and/or objective evidence the patient has experienced improvement of symptoms and/or appropriate lab values due to Ocaliva. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OFEV

## Products Affected

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results to confirm diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For a diagnosis of Idiopathic Pulmonary Fibrosis, must be prescribed by a Pulmonologist. For Systemic Sclerosis-Associated Interstitial Lung disease with declining pulmonary function or chronic fibrosing interstitial lung diseases with a progressive phenotype, must be prescribed by a Pulmonologist or Rheumatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a documented diagnosis of idiopathic pulmonary fibrosis. Covered for a diagnosis of systemic sclerosis-associated interstitial lung disease (SSC-ILD) with declining pulmonary function or a diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype when HRCT scan conducted within the past 12 months shows fibrosis affecting at least 10% of the lungs. For SSC-ILD, the patient must have failed to respond to or been intolerant of mycophenolate mofetil. For chronic fibrosing interstitial lung diseases with a progressive phenotype, patient must have clinical signs of progression (defined as FVC decline at least 10% or FVC decline at least 5% with worsening symptoms or imaging) despite treatment with one of the following withing the last 24 months: prednisone, azathioprine, mycophenolate mofetil, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# OLUMIANT

## Products Affected

- Olumiant

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist or rheumatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of severe alopecia areata, current episode documented to have been present at least 6 months, with severity of alopecia areata tool (SALT) showing hair loss encompassing at least 50% of the scalp. SALT baseline must be provided. Documentation must be submitted confirming that the patient has not had spontaneous improvement in the past 6 months (i.e., greater than a 10-point spontaneous reduction in SALT score). Documentation of a dermatoscopic evaluation showing presence of follicular ostia, exclamation point hair, yellow dots (follicular ostium filled with keratin and/or sebum), or cadaver hair (residual hair shafts visible as black dots in the follicular ostia) must be submitted to confirm the patient's diagnosis. Patient must not be experiencing other forms of alopecia (such as androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss) or any other concomitant conditions (e.g., tinea capitis, psoriasis, lupus erythematosus, atopic dermatitis, or secondary syphilis). Covered for a diagnosis of moderate to severe rheumatoid arthritis in patients with documented failure of two of the following alternatives: Enbrel, Humira, Cyltezo, Hadlima, Orencia, Rinvoq, Xeljanz/XR. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ONYCHOMYCOSIS

## Products Affected

- Jublia
- tavaborole

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis, KOH stain or culture results showing presence of trichopyton rubrum or trichophyton mentagrophytes, and documentation of previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of onychomycosis of the toenails in patients with documented culture or KOH stain positive for Trichophyton rubrum or Trichophyton mentagrophytes. Additionally, unless contraindicated, documentation of failure or severe intolerance to a course of oral terbinafine must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OPIOID-INDUCED CONSTIPATION

## Products Affected

- Relistor oral
- Relistor subcutaneous solution
- Relistor subcutaneous syringe 12 mg/0.6 mL, 8 mg/0.4 mL
- Symproic

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of opioid-induced constipation with documented lack of response or severe intolerance to generic lubiprostone or Movantik. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OPZELURA

## Products Affected

- Opzelura

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling, specifically not to be used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine. Excluded for forms of vitiligo other than nonsegmental. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist. |
| **Coverage Duration** | Initial 6 months, recert 1 year. |
| **Other Criteria** | Covered for a diagnosis of nonsegmental vitiligo in patients for whom a two-month trial with prescription strength generic topical steroids has failed to restore pigmentation to the vitiliginous skin. For patients with vitiliginous skin on the face and/or intertriginous areas where topical steroids would be inappropriate, failure of a two-month trial with topical tacrolimus to restore pigmentation to the vitiliginous skin must be documented. Covered for a diagnosis of atopic dermatitis in patients who have had serious side effects from or drug failure after at least a four-week trial with a prescription strength generic topical steroid. Must also have had serious side effects from or drug failure after at least a six-week trial with either topical tacrolimus or topical pimecrolimus. Recertification for a diagnosis of nonsegmental vitiligo will require documentation of improvement/decrease in affected areas of vitiligo from baseline based on objective and/or subjective assessment from provider. Recertification for atopic dermatitis will require the patient has achieved/maintained a positive clinical response to therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORAL ONCOLOGY

## Products Affected

- Akeega
- Alecensa
- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets,dose pack
- Augtyro
- Ayvakit oral tablet 100 mg, 200 mg, 25 mg, 300 mg, 50 mg
- Balversa oral tablet 3 mg, 4 mg, 5 mg
- Braftovi
- Cabometyx
- Caprelsa oral tablet 100 mg, 300 mg
- Cometriq
- Copiktra
- Cotellic
- Daurismo oral tablet 100 mg, 25 mg
- Erivedge
- everolimus (antineoplastic) oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg
- everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg
- Fotivda
- Fruzaqla oral capsule 1 mg, 5 mg
- Gavreto
- Gilotrif
- Ibrance
- Iclusig oral tablet 10 mg, 15 mg, 30 mg, 45 mg
- Idhifa
- imatinib oral tablet 100 mg, 400 mg
- Inlyta oral tablet 1 mg, 5 mg
- Inqovi
- Inrebic
- Iwilfin
- Jakafi oral tablet 10 mg, 15 mg, 20 mg, 25 mg, 5 mg
- Jaypirca oral tablet 100 mg, 50 mg
- Koselugo
- Krazati
- lapatinib
- Lenvima oral capsule 10 mg/day (10 mg x 1), 12 mg/day (4 mg x 3), 14 mg/day(10 mg x 1-4 mg x 1), 18 mg/day (10 mg x 1-4 mg x2), 20 mg/day (10 mg x 2), 24 mg/day(10 mg x 2-4 mg x 1), 4 mg, 8 mg/day (4 mg x 2)
- Lonsurf oral tablet 15-6.14 mg, 20-8.19 mg
- Lorbrena oral tablet 100 mg, 25 mg
- Lumakras
- Lynparza
- Lytgobi oral tablet 12 mg/day (4 mg x 3), 16 mg/day (4 mg x 4), 20 mg/day (4 mg x 5)
- Mekinist oral recon soln
- Mekinist oral tablet 0.5 mg, 2 mg
- Mektovi
- Nerlynx
- Ninlaro
- Nubeqa
- Odomzo
- Ogsiveo oral tablet 100 mg, 150 mg, 50 mg
- Ojemda oral suspension for reconstitution
- Ojemda oral tablet 500 mg/week (100 mg x 5)
- Ojjaara oral tablet 100 mg, 150 mg, 200 mg
- Onureg
- Orserdu oral tablet 345 mg, 86 mg
- pazopanib
- Pemazyre
- Piqray
- Pomalyst
- Qinlock
- Retevmo oral capsule 40 mg, 80 mg
- Rezlidhia
- Rozlytrek oral capsule 100 mg, 200 mg
- Rozlytrek oral pellets in packet
- Rubraca
- Rydapt
- Scemblix oral tablet 100 mg, 20 mg, 40 mg
- Stivarga

- Tabrecta
- Tafinlar oral capsule
- Tafinlar oral tablet for suspension
- Tagrisso
- Talzenna
- Tazverik
- Tepmetko
- Tibsovo
- Truqap
- Tukysa oral tablet 150 mg, 50 mg
- Turalio oral capsule 125 mg
- Vanflyta
- Venclexta oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack
- Verzenio
- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution
- Vizimpro
- Vonjo
- Xalkori
- Xospata
- Xpovio oral tablet 100 mg/week (50 mg x 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 80mg twice week (160 mg/week)
- Xtandi oral capsule
- Xtandi oral tablet 40 mg, 80 mg
- Zejula oral tablet 100 mg, 200 mg, 300 mg
- Zelboraf
- Zolinza
- Zydelig
- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For cancer diagnosis, must be prescribed by an oncologist or hematologist, or urologist in the case of prostate cancer. For non-cancer diagnosis, must be prescribed by an appropriate specialist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORENCIA

## Products Affected

- Orencia ClickJect
- Orencia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Orencia will not be approved for use in combination with other potent immunosuppressants, such as biologic DMARDs or Janus Kinase inhibitors. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for prophylaxis of acute graft versus host disease (in combination with a calcineurin inhibitor and methotrexate) in adults and pediatric patients at least 2 years of age undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor. Covered for the treatment of psoriatic arthritis. Covered for the treatment of active moderate to severe rheumatoid arthritis or juvenile idiopathic arthritis in patients with polyarticular disease who have intolerance or failure to respond to one of the following approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period. Orencia will not be approved for use in combination with other potent immunosuppressants, such as biologic DMARDS or Janus Kinase inhibitors. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# ORENITRAM

## Products Affected

- Orenitram
- Orenitram Month 1 Titration Kt
- Orenitram Month 2 Titration Kt
- Orenitram Month 3 Titration Kt

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies for stated diagnosis, right heart catheterization results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist or cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of pulmonary hypertension diagnosed by right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest. In addition, the patient must have a pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. There must also be documentation of clinical failure or severe intolerance to generic sildenafil or generic tadalafil/Alyq as well as an endothelin receptor antagonist, either alone or in combination. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORGOVYX

## Products Affected

- Orgovyx

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or hematologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Orgovyx will be covered for patients with advanced Prostate Cancer who have a contraindication (such as high risk for cardiovascular [CV] events or a history of CV events) or had serious side effects to two of the following: degarelix (Firmagon), leuprolide (Lupron/Eligard), or triptorelin/Trelstar. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORIAHNN

## Products Affected

- Oriahnn

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, uterine fibroids must be documented by pelvic ultrasound |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a gynecologist |
| **Coverage Duration** | Initial approval - 1 year. Recertification - 1 year. |
| **Other Criteria** | Covered for premenopausal female patients with a diagnosis of heavy menstrual bleeding associated with uterine fibroids. Pelvic ultrasound must be provided to confirm diagnosis. Patient must have had serious side effects or drug failure with a contraceptive (such as estrogen-progesterone, progesterone, or hormone-based intrauterine device) and tranexamic acid. Recertification will require objective and/or subjective evidence from provider of improved symptoms. Treatment beyond 24 months (two 12-month courses) will not be approved. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORILISSA

## Products Affected

- Orilissa oral tablet 150 mg, 200 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for patients with severe hepatic impairment (Child-Pugh C) and as limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a gynecologist |
| **Coverage Duration** | Dyspareunia/moderate hepatic impairment: 6 mos max. Other: auth 6 mos, recert 18 mos. (24 mos max) |
| **Other Criteria** | Covered for a diagnosis of pain associated with endometriosis. In addition, the patient must have a lack of clinical response, intolerance, or contraindication to at least one prescription strength nonsteroidal anti-inflammatory drug (NSAID) used in combination with hormonal therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORKAMBI

## Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage will be excluded in patients with Cystic Fibrosis who are not homozygous for the F508del mutation in the CFTR gene. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic results to include testing that shows two copies of the F508 del mutation in the conductance regulator (CFTR) gene. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OTEZLA

## Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For Psoriatic Arthritis and Plaque Psoriasis, prescriber must be a Dermatologist or Rheumatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Otezla is covered for the diagnosis of oral ulcers associated with Bechet's disease. Covered for patients with a diagnosis of mild, moderate, or severe chronic plaque psoriasis that involves at least 2% body surface area. Covered for the diagnosis of mild, moderate, or severe chronic plaque psoriasis in patients if the affected area involves the hands, feet, facial or genital regions. Patients also must meet one of the following criteria: 1) had a 3-month trial of acitretin, methotrexate, or cyclosporine therapy resulting in intolerance or clinical failure or 2) have tried UVB/coal tar or PUVA/topical corticosteroids for at least 3 months or 3) have tried and failed at least two of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Otezla is covered for patients with a diagnosis of psoriatic arthritis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OXBRYTA

## Products Affected

- Oxbryta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial approval - 1 year. Recertifications - 2 years. |
| **Other Criteria** | Covered for treatment of sickle cell disease in patients who have had at least one prior vaso-occlusive crises (VOC) in previous 12 months. Examples of VOC events include, but are not limited to, acute episode of pain caused by VOC, acute chest syndrome, hepatic sequestration, splenic sequestration, or priapism. In addition, patient must have experienced inadequate pain relief with a minimum three-month trial or a hematologic toxicity reaction with hydroxyurea. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use. Recertification after initial one year approval requires evidence of a decrease in VOC frequency from baseline, attributable to use of Oxbryta. Subsequent recertifications require evidence of ongoing decreased VOC frequency from baseline. Requires requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OXERVATE

## Products Affected

- Oxervate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an ophthalmologist. |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | Covered for a diagnosis of stage 2 (persistent epithelial defect, ped) or stage 3 (corneal ulcer) Neurotrophic Keratitis (NK). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PAIN MANAGEMENT

## Products Affected

- fentanyl citrate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the management of breakthrough pain in individuals with cancer that are opioid-tolerant. In addition, there must be documentation of failure or severe intolerance to at least two other opioid medications. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PALYNZIQ

## Products Affected

- Palynziq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies for stated diagnosis, serum phenylalanine levels, and any other pertinent lab/diagnostic test results (such as genetic test results) performed to confirm the diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a healthcare provider experienced in the management of PKU |
| **Coverage Duration** | Initial approval - 1 year. Recertifications - 2 years. |
| **Other Criteria** | Covered for a diagnosis of phenylketonuria (PKU) with hyperphenylalanemia (HPA). In addition to diagnosis, there must be documentation of elevated blood phenylalanine level (greater than 600 micro-mol per liter). Patient must have failed to respond to treatment with Kuvan (sapropterin) for a period of no less than 30 days. Upon recertification, coverage will not be extended for patients who have not responded to therapy. Response to therapy is defined as a reduction of blood phenylalanine concentration from pre-treatment baseline after at least 16 weeks of continuous treatment with the maximum tolerated dose. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PARKINSONS

## Products Affected

- Gocovri oral capsule,extended release 24hr 137 mg, 68.5 mg
- Inbrija inhalation capsule, w/inhalation device
- Nourianz

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist |
| **Coverage Duration** | One year |
| **Other Criteria** | For the treatment of off episodes in Parkinson's disease, Gocovri, Inbrija, and Nourianz are covered for patients who have had inadequate therapeutic response or severe intolerance to TWO generic anti-Parkinson's disease drugs with different mechanisms of action. Examples include COMT inhibitors (entacapone and tolcapone), dopamine agonists (pramipexole, ropinirole, amantadine, and bromocriptine), MAO B-inhibitors (rasagiline and selegiline), and anticholinergics (benztropine). For the treatment of dyskinesia associated with Parkinson's disease, Gocovri is covered in combination with levodopa/carbidopa in patients who have had inadequate response with or severe intolerance to immediate-release amantadine. Recertification for the treatment of off episodes will require objective and/or subjective evidence from prescriber of a decrease in frequency and/or severity of wearing-off symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# PIRFENIDONE

## Products Affected

- pirfenidone oral capsule
- pirfenidone oral tablet 267 mg, 534 mg, 801 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results to confirm diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a documented diagnosis of idiopathic pulmonary fibrosis. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PROCYSBI

## Products Affected

- Procysbi oral granules del release in packet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Hypersensitivity to penicillamine and as limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a nephrologist, genetic or metabolic specialist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of nephropathic cystinosis in patients who have demonstrated therapeutic failure, contraindication, or intolerance to immediate release cysteamine/Cystagon. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PROLIA

## Products Affected

- Prolia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, DEXA scan results, previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Patient must fall into one of the following categories and be at high risk of fracture: 1) postmenopausal woman, 2) osteoporosis in a male or 3) patient at risk for steroid induced osteoporosis. High risk for fracture is defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy. Prolia will also be covered to increase bone mass in men at high risk of fracture receiving androgen deprivation therapy (bilateral orchiectomy or GnRH-agonist therapy) for non-metastatic prostate cancer. Prolia will be covered to increase bone mass in women at high risk of fracture receiving adjuvant aromatase inhibitor therapy (such as anastrozole, exemestane, or letrozole) for breast cancer. Request will also be evaluated for part B versus part D coverage and off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PROMACTA

## Products Affected

- Promacta oral powder in packet 12.5 mg, 25 mg
- Promacta oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | For ITP or aplastic anemia, must be prescribed by a Hematologist. For thrombocytopenia with Hep C, must be prescribed by GI, Hepatologist, Infectious Disease, or HCV/HIV specialist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of chronic immune thrombocytopenia purpura (ITP) in patients who have experienced an insufficient response to previous treatment with either corticosteroids or immunoglobulins (IVIG). Insufficient response is defined as a platelet count of less than 30,000/microliter or greater than 30,000/microliter but with bleeding symptoms. Covered for a diagnosis of thrombocytopenia in patients with chronic Hepatitis C to allow initiation and maintenance of interferon-based therapy. Covered for first-line treatment of severe aplastic anemia, in combination with standard immunosuppressive therapy. Covered for severe refractory aplastic anemia in patients who have experienced an insufficient response to immunosuppressive therapy (such as antithymocyte globulin (ATG) alone or in combination with cyclosporine and/or a corticosteroid). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | Yes |

# PROPHYLACTIC HAE

## Products Affected

- Cinryze
- Haegarda
- Orladeyo
- Takhzyro subcutaneous solution
- Takhzyro subcutaneous syringe 150 mg/mL, 300 mg/2 mL (150 mg/mL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for acute hereditary angioedema attacks. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by allergist, immunologist, hematologist, or dermatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a confirmed diagnosis of HAE type 1, type II, or type III. Prophylactic therapy will be covered for individuals whose provider has determined that prophylactic therapy is medically necessary, after consideration of such factors as disease burden, activity of disease, frequency of attacks, patient preference, quality of life, and availability of healthcare resources. Objective and/or subjective documentation of these considerations must be provided. Requests for Cinryze for long-term prophylaxis will require documentation of therapeutic failure, severe intolerance, or a contraindication to both Haegarda and Takhzyro (this step is not required for short-term prophylaxis prior to medical, surgical, or dental procedure). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PULMONARY HYPERTENSION

## Products Affected

- Alyq
- ambrisentan oral tablet 10 mg, 5 mg
- bosentan oral tablet 125 mg, 62.5 mg
- Opsumit
- Opsynvi
- sildenafil (Pulmonary Arterial Hypertension) oral tablet
- tadalafil (pulmonary arterial hypertension) oral tablet 20 mg
- Tadliq
- Tracleer oral tablet for suspension
- Uptravi oral tablet 1,000 mcg, 1,200 mcg, 1,400 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg
- Uptravi oral tablets,dose pack

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, right heart catheterization results |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist or cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of pulmonary arterial hypertension diagnosed by right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest. In addition, the patient must have a pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Nebulized products will also be evaluated for part B versus part D coverage. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PYRUKYND

## Products Affected

- Pyrukynd oral tablet 20 mg, 5 mg, 5 mg (4-week pack), 50 mg
- Pyrukynd oral tablets,dose pack

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Also, Pyrukynd will not be covered for patients who are homozygous for the c.1436G to A (p.R479H) variant or have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by a hematologist, geneticist, or provider who specializes in pyruvate kinase (PK) deficiency |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Covered for patients with a diagnosis of pyruvate kinase deficiency hemolytic anemia defined as having documented presence of at least 2 mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, one of which is a missense mutation. Baseline hemoglobin must be less than or equal to 10 g/dL OR have had more than 4 red blood cell (RBC) transfusions in the last year. Recert requires ONE of the following: a) Increase in hemoglobin greater than 1.5 mg/dL from baseline OR b) Reduction in the number of RBC transfusions while receiving Pyrukynd OR c) Laboratory evidence demonstrating improvement in markers of hemolysis (i.e., indirect bilirubin, lactate dehydrogenase (LDH), haptoglobin), OR d) other subjective or objective evidence from provider that use of Pyrukynd has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |

# QUININE SULFATE

## Products Affected

- quinine sulfate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for the treatment of leg cramps. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Quinine sulfate is covered for the treatment of malaria infections. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RADICAVA

## Products Affected

- Radicava ORS Starter Kit Susp

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a provider that specializes in Amyotrophic lateral sclerosis (ALS) and/or neuromuscular disorders |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of Amyotrophic Lateral Sclerosis (ALS) in adult patients. Recertification requires subjective or objective evidence from provider that use of Radicava has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RAVICTI

## Products Affected

- Ravicti

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by physician experienced in the management of urea cycle disorders. |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RECORLEV

## Products Affected

- Recorlev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Excluded for individuals with pituitary or adrenal carcinoma and will not be covered for a treatment of fungal infections. |
| **Required Medical Information** | Diagnosis, mean urinary free cortisol (UFC) level measured over three 24-hour measurements, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for a diagnosis of endogenous Cushing's syndrome in patients with documentation of clinical symptoms (such as diabetes, central obesity, moon face, buffalo hump, osteoporosis, muscle wasting, hypertension, depression, and anxiety) who have a mean urinary free cortisol (UFC) level that is at least 1.5x the upper limit of normal (ULN) measured over three 24-hour measurements (ULN = 50 mcg/24 hours or 138 nmol/24 hours). Also, there must be documentation of failure of or contraindication to Cushing's syndrome-specific surgery as well as serious side effects or drug failure with oral ketoconazole. For patients with a diagnosis of Cushing's Disease (Cushing's Syndrome that is caused by a pituitary adenoma), documentation of trial and failure or serious side effects with Signifor/pasireotide must be provided. Recertification at 6 months and yearly thereafter will require laboratory results to document a recent UFC level within normal limits AND improvement in symptoms of Cushing's Syndrome. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# RELTONE

## Products Affected

- Reltone oral capsule 200 mg, 400 mg
- ursodiol oral capsule 200 mg, 400 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of radiolucent, non-calcified gallstones in patients for whom elective cholecystectomy is medically inappropriate, as attested by provider. Covered for the prevention of gallstones in obese patients experiencing rapid weight loss. For all indications, documentation of contraindication to generic ursodiol 300 mg capsules and generic ursodiol tablets is required before the approval of Reltone, ursodiol 200 mg and 400 mg capsules. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REVCOVI

## Products Affected

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA-approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an immunologist, hematologist-oncologist, or physician who specializes in the treatment of ADA-SCID. |
| **Coverage Duration** | Initial approval - 1 year. Recertification - 2 years. |
| **Other Criteria** | Covered for patients with a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) that has been confirmed by either: 1) absent or very low (less than 1% of normal) adenosine deaminase (ADA) catalytic activity in the plasma, urine, or dried blood spots prior to the initiation of enzyme replacement therapy or 2) molecular genetic testing confirming bi-allelic mutations in the ADA gene. Patients must also have elevated deoxyadenosine triphosphate (dATP) levels or total deoxyadenosine (dAdo) nucleotides in erythrocytes (red blood cells) compared to a laboratory standard. Recertification every 2 years thereafter will require documentation of a positive response to treatment such as one or more of the following: a. Improvement in immune status (total lymphocyte and B, T, and natural killer (NK) lymphocyte counts, quantitative immunoglobulin (Ig) concentration [IgG, IgA, IgM]) b. Improvement in clinical status (infection rate, incidence and duration of hospitalization, and performance status) c. Normalization of plasma ADA activity, erythrocyte dATP or total dAdo nucleotide levels compared to a laboratory standard or d. other subjective or objective evidence from provider that use of Revcovi has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |

**Prior Authorization Requirements**
**Effective September 1, 2024**

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REZUROCK

## Products Affected

- Rezurock

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a healthcare provider experienced in the management of transplant rejection and/or graft-versus-host disease. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 2 years. |
| **Other Criteria** | Covered for patients with a diagnosis of chronic graft-versus-host disease (cGVHD) who have had inadequate response or intolerance with at least 2 prior lines of therapy, one of which must be Imbruvica/ibrutinib. For patients on a proton pump inhibitor (PPI) (e.g., omeprazole, esomeprazole, lansoprazole), an attempt must be made to discontinue the PPI and switch to an H2 receptor antagonist (e.g., famotidine) to allow for once daily dosing of Rezurock. Upon recert, documentation of positive response to therapy must be provided. Positive response is defined as resolution of all manifestations in each organ or site, or improvement in at least one organ or site without progression in any other organ or site. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RINVOQ

## Products Affected

- Rinvoq oral tablet extended release 24 hr
  15 mg, 30 mg, 45 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an allergist, dermatologist, gastroenterologist, or rheumatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) in pts who have had serious side effects or drug failure w/ one of the following: Humira, Cyltezo, Hadlima, or Enbrel. TNF-blocker-experienced pts must have had serious side effects or drug failure with any AS-indicated TNF-blocker. Covered for moderate to severe ATOPIC DERMATITIS (AD) involving at least 10% body surface area (BSA). In addition, pt must have received treatment with TWO of the following treatment options during the six months preceding the request: 1) treatment with high-potency topical steroid for minimum 14-day duration or treatment with medium potency topical steroid for minimum 28-day duration, 2) treatment w/ topical tacrolimus, 3) treatment w/ an oral or injectable immunosuppressant, such as a steroid indicated or compendia-supported for treatment of AD, 4) treatment with systemic therapy indicated or compendia-supported for treatment of AD. Covered for moderately to severely active CROHN's disease (CD) or ULCERATIVE COLITIS (UC) who have had serious side effects or drug failure with either Humira, Cyltezo, or Hadlima. TNF-blocker-experienced patients must have had serious side effects or drug failure with any Crohn's or UC-indicated TNF-blocker. Covered for the diagnosis of NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS in patients with documented failure of Cimzia. Covered for PSORIATIC |

| PA Criteria | Criteria Details |
|---|---|
| | ARTHRITIS (PsA) in pts who have had serious side effects or drug failure with either Humira, Cyltezo, Hadlima, or Enbrel. TNF-blocker-experienced pts must have had serious side effects or drug failure with any PSA-indicated TNF-blocker. Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant of approved disease modifying anti-rheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination, for a 3-month period. In addition, the patient must have had serious side effects or drug failure with either Humira, Cyltezo, Hadlima, or Enbrel. TNF-blocker-experienced patients must have had serious side effects or drug failure with any RA-indicated TNF-blocker. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SAMSCA

## Products Affected

- tolvaptan oral tablet 15 mg, 30 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SAPROPTERIN

## Products Affected

- sapropterin

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, baseline serum phenylalanine level, current/recent phenylalanine level with each recertification |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial approval - 2 months. Recertifications - 1 year. |
| **Other Criteria** | Covered as adjunct therapy for patients diagnosed with phenylketonuria (PKU). Initial approval will be for 2 months. Phenylalanine (PHE) levels should be checked one week after initiation of therapy. If PHE levels do not decrease from baseline on a 10mg/kg/day dose, the dose may be increased to 20mg/kg/day. If PHE levels do not decrease from baseline after 2 months, the patient is considered a non-responder and further therapy will not be authorized. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis. For the diagnosis of Cushings disease, there must be pertinent lab/diagnostic test results, which include a mean urine free cortisol (mUFC) level at baseline and upon recertification. Confirmation from provider that patient is not a candidate for surgery or that previous surgery was not effective. A non-surgical candidate is defined as either having a medical contraindication to surgery or having a tumor which is surgically unapproachable. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist. |
| **Coverage Duration** | Initial approval - 3 months. Recertifications - 1 year. |
| **Other Criteria** | After 3 months of therapy for a diagnosis of Cushings disease, patient must demonstrate a reduction in mUFC compared to baseline. Subsequent authorizations will be for 12 months with continued signs of efficacy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SILIQ

## Products Affected

- Siliq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a Dermatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of moderate to severe plaque psoriasis that involves at least 5% body surface area (BSA). Covered for the diagnosis of moderate to severe plaque psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. In addition, there must be documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIMLANDI

## Products Affected

- Simlandi(CF) Autoinjector

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) for pts w/ refractory disease defined by failure of at least one NSAID at maximally tolerated dose for at least 1 month. Covered for moderate to severe active CROHN'S DISEASE. In addition, the patient must meet ONE of the following criteria: 1) patient continues to experience disease flare despite at least 4 weeks of maximally tolerated budesonide, up to 9mg/day (or equivalent therapeutic glucocorticoid), 2) treatment with an immunomodulator (such as azathioprine or 6-mp) fails to maintain remission in a case of steroid dependent or steroid refractory disease, 3) documentation is provided that azathioprine, 6-mp, or MTX is not effective, contraindicated, or not tolerated. Covered for moderate to severe HIDRADENITIS SUPPURATIVA. Covered for moderate to severely active JUVENILE IDIOPATHIC ARTHRITIS (JIA). Pt must have failed to respond to or are intolerant to approved DMARD agents, such as MTX, NSAIDS, analgesics or corticosteroids, either alone or in combination. Covered for moderate to severe chronic PLAQUE PSORIASIS that involves at least 5% of their body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patient also must meet one of the following criteria (requirement bypassed if patient has tried UVB and coal tar or PUVA and topical corticosteroids--a non- |

| PA Criteria | Criteria Details |
|---|---|
| | part- d service): 1) had a 3-month trial of acitretin, methotrexate (MTX), or cyclosporine therapy resulting in intolerance or clinical failure OR 2) have tried and failed at least TWO of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for PSORIATIC ARTHRITIS (PsA). Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as MTX, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in pts with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. Covered for non-infectious intermediate, posterior uveitis and panuveitis in pts with an ineffective response, contraindication, or intolerance to TWO of the following regimens: 1) topical or injected ophthalmologic steroid, 2) oral systemic steroid, 3) immunosuppressive agent, such as azathioprine, mycophenolate, or MTX. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIMPONI

## Products Affected

- Simponi subcutaneous pen injector 100 mg/mL, 50 mg/0.5 mL
- Simponi subcutaneous syringe 100 mg/mL, 50 mg/0.5 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, current and previous therapies for stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of ankylosing spondylitis in patients with documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Xeljanz/XR. Covered for patients with a diagnosis of psoriatic arthritis in patients with documented failure of two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Orencia, Rinvoq, Stelara, Xeljanz/XR. Covered for the diagnosis of rheumatoid arthritis in patients with documented failure to two of the following alternatives: Enbrel, Humira, Orencia, Rinvoq, Xeljanz/XR. Covered for the diagnosis of moderately to severely active ulcerative colitis in patients with documented failure of TWO of the following: Humira, Stelara, Rinvoq, Xeljanz/XR. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIVEXTRO

## Products Affected

- Sivextro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results (such as bacterial cultures or antibiotic sensitivity testing), and documentation of previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 days |
| **Other Criteria** | Sivextro is covered when prescribed or recommended by an Infectious Disease specialist. When prescribed by any other prescriber, laboratory data including culture site, organism identified and susceptibility must accompany prior-authorization request and documentation must support the trial. In addition, documentation of therapeutic failure of at least one first-line antibacterial agent that is clinically appropriate for the organism identified must be submitted. Approval will be for 6 days of therapy. Requests for non-FDA approved durations of therapy will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SKYCLARYS

## Products Affected

- Skyclarys

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic/genetic test results. Baseline modified Friedreich's Ataxia Rating Scale (mFARS) score must be provided. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or prescriber knowledgeable in the management of Friedreich's ataxia (FA). |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of Friedreich's ataxia confirmed by genetic testing. In addition, the patient must exhibit clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling). Recertification requests will require documentation that the patient has had a clinical benefit from therapy (e.g., slowed decline in limb coordination) OR patient has had a reduction in modified Friedreich's Ataxia Rating Scale (mFARS) score of at least 1.5 points from baseline OR provider attestation that the patient continues to benefit from therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SKYRIZI

## Products Affected

- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous wearable injector 180 mg/1.2 mL (150 mg/mL), 360 mg/2.4 mL (150 mg/mL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist, gastroenterologist, or rheumatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of moderately to severely active CROHN's DISEASE in patients who have failed to achieve remission with at least 6 weeks of corticosteroid treatment or in corticosteroid dependent or refractory patients who fail to maintain remission with an immunomodulator (such as azathioprine, 6-mp, or MTX). Covered for patients with a diagnosis of moderate to severe chronic PLAQUE PSORIASIS that involves at least 5% body surface area. Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patients also must meet one of the following criteria: 1) had a 3-month trial of acitretin, methotrexate, or cyclosporine therapy resulting in intolerance or clinical failure or 2) have tried UVB/coal tar or PUVA/topical corticosteroids for at least 3 months or 3) have tried and failed at least two of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for the treatment of active PSORIATIC ARTHRITIS. Covered for the diagnosis of moderately to severely ULCERATIVE COLITIS in patients with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. |

| PA Criteria | Criteria Details |
|---|---|
| | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SLEEP DISORDERS

## Products Affected

- armodafinil
- modafinil
- sodium oxybate
- Sunosi oral tablet 150 mg, 75 mg
- Wakix oral tablet 17.8 mg, 4.45 mg
- Xyrem
- Xywav

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, sleep study results, and documentation of outcome with previous therapies attempted for the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or sleep specialist for a diagnosis of cataplexy or excessive daytime sleepiness associated with narcolepsy. Must be prescribed by a neurologist, sleep specialist, or pulmonologist for a diagnosis of Excessive Daytime Sleepiness associated with Obstructive Sleep Apnea. |
| **Coverage Duration** | One year |
| **Other Criteria** | Armodafinil and modafinil are covered for a diagnosis of excessive daytime sleepiness associated with narcolepsy, excessive daytime sleepiness associated with obstructive sleep apnea (OSA) and shift-work disorder. Sunosi, Wakix, Xyrem/sodium oxybate, and Xywav are covered for a diagnosis of excessive daytime sleepiness associated with narcolepsy for adult patients who have had severe intolerance to or therapeutic failure of both armodafinil and modafinil (armodafinil and modafinil not required in pediatric patients). Sunosi is covered for a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) for patients who have had severe intolerance to or therapeutic failure of both armodafinil and modafinil. Xywav is covered for a diagnosis of idiopathic hypersomnia. Wakix, Xyrem/sodium oxybate, and Xywav are covered for a diagnosis of cataplexy associated with narcolepsy. Documentation of OSA or narcolepsy within sleep study results must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |

**Prior Authorization Requirements**
**Effective September 1, 2024**

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# STELARA

## Products Affected

- Stelara subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of moderate to severe active Crohn's disease. In addition, the patient must meet one of the following criteria: 1) patient continues to experience disease flare despite complete and adequate therapy with a corticosteroid. 2) treatment with an immunomodulator (such as azathioprine or 6-mp) fails to maintain remission in a case of steroid-dependent or steroid-refractory disease. 3) documentation is provided that azathioprine, 6-mp, or methotrexate is not effective, contraindicated, or not tolerated. Covered for patients with a diagnosis of moderate to severe chronic plaque psoriasis that involves at least 5% body surface area. Covered for the diagnosis of moderate to severe chronic plaque psoriasis in patients with less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. Patients also must meet one of the following criteria: 1) had a 3-month trial of acitretin, methotrexate, or cyclosporine therapy resulting in intolerance or clinical failure or 2) have tried UVB/coal tar or PUVA/topical corticosteroids for at least 3 months or 3) have tried and failed at least two of the following for 3 months: treatment with medium and/or high potency topical corticosteroids or anthralin, calcipotriene, or tazarotene. Covered for the diagnosis of psoriatic arthritis. Covered for the diagnosis of moderately to severely ulcerative colitis in patients with documented failure of TWO standard of care classes: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. DOSING: |

| PA Criteria | Criteria Details |
|---|---|
| | For patients with a diagnosis of psoriasis weighing less than or equal to 100kg, 45mg dose will be approved. For patients with a diagnosis of psoriasis weighing greater than 100kg, 90mg dose will be approved. For patients with a diagnosis of psoriatic arthritis, 45mg dose will be approved. Initial dosing for psoriasis and psoriatic arthritis is at weeks 0, 4, 12 and then every 12 weeks thereafter. For patients with coexistent psoriatic arthritis and moderate to severe plaque psoriasis and who weigh more than 100kg, a 90mg starting dose will be authorized. Initial dosing is at weeks 0, 4, 12 and then every 12 weeks thereafter. For patients with Crohn's disease, weight-dependent induction dosing at week zero and the maintenance dose of 90mg every 8 weeks thereafter will be authorized. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYMDEKO

## Products Affected

- Symdeko oral tablets, sequential 100-150 mg (d)/ 150 mg (n), 50-75 mg (d)/ 75 mg (n)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage will be excluded in patients that lack the required genetic mutation(s) targeted by the medication. |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic results to include testing that shows either two copies of the F508 del mutation in the conductance regulator (CFTR) gene or at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor (Symdeko). Responsive mutations are those outlined in FDA labeling. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYNDROS

## Products Affected

- Syndros

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. For a diagnosis of nausea and vomiting associated with cancer chemotherapy, also list previous therapies. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Anorexia due to AIDS - 1 year. Chemo-induced nausea/vomiting - 6 months. |
| **Other Criteria** | Covered for the treatment of nausea and vomiting associated with cancer chemotherapy with documented lack of response or severe intolerance to one 5HT-3 receptor antagonist. Covered for treatment of anorexia associated with weight loss in patients with AIDS. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TADALAFIL FOR DAILY USE

## Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tadalafil for daily use will not be covered for the independent diagnosis of Erectile Dysfunction. Tadalafil is excluded for off-label indications even if supported by AHFS or DrugDex compendia. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of benign prostatic hyperplasia (BPH). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAFAMIDIS

## Products Affected

- Vyndamax
- Vyndaqel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic tests, including tests confirming presence of TTR amyloid in cardiac tissue such as 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a specialist experienced in the diagnosis of Transthyretin-mediated Amyloidosis (ATTR-CM), such as a cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of cardiomyopathy of wild-type (wtATTR-CM) or Hereditary Transthyretin-mediated Amyloidosis (hATTR-CM). Patient must have a medical history of NYHA class I-III heart failure with at least one prior hospitalization for heart failure or clinical evidence of heart failure requiring treatment with a diuretic for improvement. Evidence of cardiac involvement seen on echocardiography and/or cardiac magnetic imaging, such as thickened left ventricle wall or septum, must be provided. Presence of TTR amyloid in cardiac tissue must be confirmed via 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or via genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein correlated with amyloid deposits identified on cardiac biopsy. Upon recertification, there must be documentation that the patient continues to obtain clinical benefit from the therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# TALTZ

## Products Affected

- Taltz Autoinjector
- Taltz Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist or rheumatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of ankylosing spondylitis in patients who have had documented clinical failure or severe intolerance with two of the following: Cosentyx, Enbrel, and Humira. Covered for the diagnosis of non-radiographic axial spondyloarthritis in patients with documented failure of Cimzia or Cosentyx. Covered for the diagnosis of moderate to severe chronic plaque psoriasis that involves at least 5 % body surface area (BSA). Covered for the diagnosis of moderate to severe chronic plaque psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. In addition, there must be documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara. Taltz is covered for patients with a diagnosis of psoriatic arthritis with documented failure of two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Orencia, Stelara, Xeljanz/XR. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TARPEYO

## Products Affected

- Tarpeyo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a nephrologist or provider specializing in IgA nephropathy |
| **Coverage Duration** | 10 months |
| **Other Criteria** | Covered for patients with a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy. Patient must have an eGFR greater than 35mL/min/1.73m2 and have proteinuria (defined as greater than or equal to 1 g/day or urine protein creatinine ratio (UPCR) greater than or equal to 0.8 g/g). Patient must also be on an ACE Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) at the maximally tolerated dose, unless the patient is unable to tolerate or drug class is contraindicated. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAVALISSE

## Products Affected

- Tavalisse

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of chronic immune thrombocytopenia purpura (ITP) in patients who have experienced an insufficient response to previous treatment with either corticosteroids or immunoglobulins (IVIG). Insufficient response is defined as a platelet count of less than 30,000/microliter or greater than 30,000/microliter but with bleeding symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# TAVNEOS

## Products Affected

- Tavneos

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. Must either have a positive test for antibodies to proteinase 3 (PR3) or myeloperoxidase (MPO) or have histological evidence of GPA or MPA via biopsy. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a rheumatologist, nephrologist, pulmonologist, or immunologist. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered as adjunctive treatment for patients with a diagnosis of active and severe anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]). Tavneos must be used as adjunctive treatment in combination with standard of care therapy (such as cyclophosphamide, azathioprine, mycophenolate mofetil, rituximab, glucocorticoids). Recertification will require documentation of disease remission, defined as the absence of clinical signs or symptoms attributed to GPA or MPA while on Tavneos. Recertification requires that Tavneos continue to be used in combination with standard of care therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TEGSEDI

## Products Affected

- Tegsedi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded in patients with a platelet count less than 100 x 10 to the 9th per liter or history of acute glomerulonephritis caused by Tegsedi. |
| **Required Medical Information** | Diagnosis with confirmation of the transthyretin (TTR) gene mutation |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a specialist experienced in the diagnosis of Hereditary Transthyretin-mediated Amyloidosis (hATTR), such as a hematologist, oncologist, neurologist, gastroenterologist, geneticist, or nephrologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) when the diagnosis has been confirmed by mutation of the transthyretin (TTR) gene. Patients must also have symptoms consistent with polyneuropathy, which can include either peripheral sensorimotor polyneuropathy symptoms (such as tingling or increased pain in the hands/feet/arms, loss of feeling in the hands/feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking, seizures, headaches) or autonomic neuropathy symptoms (such as orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomic symptoms of constipation, diarrhea, nausea, vomiting, anorexia, and early satiety). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

# TERIPARATIDE

## Products Affected

- teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, DEXA scan report(s), previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Two years (refer to other criteria section) |
| **Other Criteria** | Patient must fall into one of the following categories: postmenopausal woman, primary or hypogonadal osteoporosis in a male or patient at risk for steroid induced osteoporosis. Patient must also be at high risk for a fracture defined as 1) history of previous osteoporosis-related fracture, 2) T-score of -2.5 SD or less, 3) T-score between -1.0 and -2.5 SD below normal and a FRAX score for hip fracture of 3% or greater or the risk for other bone fracture is 20% or greater. Patient must also have experienced therapeutic failure, severe intolerance or a contraindication to an oral bisphosphonate or be an inappropriate candidate for oral bisphosphonate therapy based on clinical presentation. Therapeutic failure is defined as a decrease in bone mineral density or a fracture while on bisphosphonate therapy. Severe intolerance defined as chest pain, difficulty swallowing, intense abdominal pain, or chronic dyspepsia when oral bisphosphonate therapy was taken according to manufacturer recommendations. Oral bisphosphonates may be clinically inappropriate for a patient that is bed-ridden/unable to sit upright for 30 minutes unsupervised or has esophageal ulcerations, esophageal stricture, Barrett's esophagitis, or active ulcers. In patients without a trial of or contraindication to oral bisphosphonates, a trial with an injectable bisphosphonate will be accepted in lieu of oral, but is not required. Use of teriparatide for more than 2 years during a patient's |

| PA Criteria | Criteria Details |
|---|---|
| | lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture. Requests for continued therapy beyond 2 years will require provider attestation that the patient has remained at or has returned to having a high risk for fracture. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# THALOMID

## Products Affected

- Thalomid oral capsule 100 mg, 150 mg, 200 mg, 50 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TOPICAL PSORIASIS COMBOS

## Products Affected

- calcipotriene-betamethasone
- Duobrii
- Enstilar

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of Psoriasis. In addition, there must be lack of clinical response or intolerance to one topical steroid and either a topical vitamin D analog or a topical retinoid. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TOPICAL RETINOIDS

## Products Affected

- adapalene topical cream
- adapalene topical gel 0.3 %
- adapalene topical swab
- Altreno
- Arazlo
- Differin topical lotion
- Fabior
- tazarotene
- Tazorac topical cream 0.05 %
- Tazorac topical gel
- tretinoin topical

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used for cosmetic purposes. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Adapalene, tazarotene/Tazorac, and tretinoin products will be approved for the diagnosis of acne vulgaris. In addition, tazarotene/Tazorac will be approved for the diagnosis of plaque psoriasis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TREMFYA

## Products Affected

- Tremfya

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist or rheumatologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of moderate to severe plaque psoriasis that involves at least 5% body surface area (BSA). Covered for the diagnosis of moderate to severe plaque psoriasis that involves less than 5% BSA if the affected area involves the hands, feet, facial or genital regions. In addition, there must be documented failure to two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara. Covered for patients with a diagnosis of psoriatic arthritis in patients with documented failure of two of the following alternatives: Cosentyx, Enbrel, Humira, Otezla, Orencia, Stelara, Xeljanz/XR. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRIKAFTA

## Products Affected

- Trikafta oral tablets, sequential 100-50-75 mg(d) /150 mg (n), 50-25-37.5 mg (d)/75 mg (n)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage will be excluded in patients that lack the required genetic mutation(s) targeted by the medication. |
| **Required Medical Information** | Diagnosis, genetic test results showing at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic tests used to confirm diagnosis, current and previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or dermatologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VERKAZIA

## Products Affected

- Verkazia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an ophthalmologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of vernal keratoconjunctivitis (VKC). The patient must have had serious side effects or drug failure to an ophthalmic antihistamine with mast cell stabilizer properties (such as olopatadine, azelastine, or epinastine) OR an antihistamine eye drop in combination with a mast cell stabilizer (such as cromolyn, Alocril or Alomide). In addition, the patient must have had persistent symptoms despite treatment with an ophthalmic steroid or an inability to titrate off ophthalmic steroids. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VERQUVO

## Products Affected

- Verquvo oral tablet 10 mg, 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a Cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of symptomatic chronic heart failure with ejection fraction less than 45% in patients following a hospitalization for heart failure (within past 6 months) or need for outpatient IV diuretics (within past 3 months). Patient must also be stable on standard of care HF treatment (ARNI/ACE-I/ARB plus BB). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VIJOICE

## Products Affected

- Vijoice oral granules in packet
- Vijoice oral tablet 125 mg, 250 mg/day (200 mg x1-50 mg x1), 50 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. There must be submitted documentation of a mutation in the PIK3CA gene and the patient must have at least one target lesion identified on imaging at baseline. Recertification will require documentation from provider of objective or subjective evidence that patient has derived clinical benefit from the use of Vijoice. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VIVJOA

## Products Affected

- Vivjoa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Vivjoa is contraindicated in those who have the ability to become pregnant, are pregnant, or are lactating. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Limited to one treatment course (14 weeks) per year. |
| **Other Criteria** | Covered for a diagnosis of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential. Females who are not of reproductive potential are defined as persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g. tubal ligation, hysterectomy, salpingo-oophorectomy). The patient must have had 3 or more symptomatic acute episodes of VVC within the past 12 months and must have a KOH stain or other positive diagnostic culture test for this recurrence. In addition, the patient must have experienced an adverse reaction or treatment failure of oral fluconazole at a dosing regimen appropriate for diagnosis of RVVC, unless patient has adverse reaction or contraindication to fluconazole. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VORICONAZOLE (IV)

## Products Affected

- voriconazole intravenous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling and excluded for any non-FDA approved or non-medically accepted use, including, but not limited to, preparations such as foot baths, nasal rinses, and mouthwashes. |
| **Required Medical Information** | Diagnosis, culture results showing presence of susceptible fungal elements. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an infectious disease specialist or other prescriber specializing in the organ system affected by fungal infection. |
| **Coverage Duration** | Initial - 3 mos. Recert: 3 mos if specialist attestation of need for prolonged duration of therapy. |
| **Other Criteria** | Covered for FDA approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# WELIREG

## Products Affected

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, diagnostic test results showing germline VHL alteration |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist, urologist, nephrologist or provider who specializes in von Hippel-Lindau (VHL) disease. |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Covered for treatment of advanced renal cell carcinoma in adults following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). Covered for patients with a diagnosis of von-Hippel-Lindau disease who have a confirmed germline VHL alteration and require therapy for one of the following: renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastoma, or pancreatic neuroendocrine tumor (PNET). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XELJANZ

## Products Affected

- Xeljanz oral solution
- Xeljanz oral tablet
- Xeljanz XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the diagnosis of ankylosing spondylitis (AS). In addition, the patient must have had serious side effects or drug failure w/ one of the following: Humira, Cyltezo, Hadlima, or Enbrel. TNF-blocker-experienced patients must have had serious side effects or drug failure with any AS-indicated TNF-blocker. Covered for the treatment of polyarticular course juvenile idiopathic arthritis in pts who have had inadequate response or intolerance to methotrexate (MTX) or another disease-modifying anti-rheumatic drug (DMARD) and documented failure w/ one of the following: Enbrel, Humira, Cyltezo, Hadlima. Covered for the treatment of active psoriatic arthritis (PsA) in combination with a nonbiologic DMARD. In addition, patients must have had serious side effects or drug failure w/ one of the following: Humira, Cyltezo, Hadlima or Enbrel. TNF-blocker-experienced patients must have had serious side effects or drug failure with any PsA-indicated TNF-blocker. Covered for the treatment of moderate to severely active rheumatoid arthritis (RA) for patients who have had an inadequate response or intolerance to MTX as monotherapy or in combination with another non-biologic DMARD. For those with a contraindication to MTX, documentation of inadequate response or intolerance to an alternate DMARD appropriate for the treatment of RA is required. In addition, patients must have had serious side effects or drug failure w/ one of the following: Humira, Cyltezo, Hadlima, or Enbrel. |

| PA Criteria | Criteria Details |
|---|---|
| | TNF-blocker-experienced patients must have had serious side effects or drug failure with any RA-indicated TNF-blocker. Covered for adult patients with moderately to severely active ulcerative colitis (UC) with documented failure of ONE first-line standard of care class: thiopurine, 5-aminosalyicylate, cyclosporine, or IV/oral steroids. In addition, patient must have had serious side effects or drug failure with Humira, Cyltezo, or Hadlima if TNF-naive. TNF blocker-experienced patients must have had serious side effects or drug failure with any UC-indicated TNF blocker. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XENAZINE

## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One year |
| **Other Criteria** | Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | For the treatment of carcinoid syndrome diarrhea, coverage will not be provided in the absence of concurrent somastatin analog therapy (lanreotide or octreotide). |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist, hematologist, endocrinologist, or gastroenterologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of carcinoid syndrome diarrhea with documentation of continued diarrhea despite a minimum 3-month trial of somastatin analog therapy (lanreotide or octreotide). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XGEVA

## Products Affected

- Xgeva

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Xgeva will not be approved for use in combination with oral or injectable bisphosphonates. |
| **Required Medical Information** | Documentation of diagnosis. For a diagnosis of bone metastasis from solid tumor, provide radiographic evidence (X-ray, CT, or MRI) of a least one bone metastasis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors for which there is radiographic evidence of at least one bone metastasis. Approved for treatment of giant cell tumor of the bone (in adults and skeletally mature adolescents) that is unresectable or where surgical resection is likely to result in severe morbidity. Approved for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XHANCE

## Products Affected

- Xhance

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent lab/diagnostic tests used to confirm diagnosis, current and previous therapies |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an allergist, immunologist, otolaryngologist, or pulmonologist |
| **Coverage Duration** | Initial approval 6 mos., recert every 1 yr thereafter. |
| **Other Criteria** | Covered for chronic rhinosinusitis WITH nasal polyps (CRSwNP) if inadequate response to at least a 3-month trial with generic mometasone nasal spray at nasal polyp dosing. Covered for a diagnosis of chronic rhinosinusitis WITHOUT nasal polyps (CRSsNP) if failure or contraindications to generic fluticasone nasal spray AND generic mometasone nasal spray. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Xolair is excluded in patients weighing over 150kg. Xolair will not be covered for the treatment of atopic dermatitis. |
| **Required Medical Information** | Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for the treatment of MODERATE TO SEVERE PERSISTENT ASTHMA. The patient must be maintained on asthma treatment consistent with the GINA or NHLBI guidelines, which recommend the combination of a high-dose inhaled steroid with a long-acting beta agonist (preferred by GINA guidelines), or leukotriene inhibitor, or long-acting muscarinic antagonist, or theophylline. For patients ages 12 and older, pt. must be experiencing asthma exacerbations and the patient must have baseline IgE levels between 30 and 700 iu/ml. For patients ages 6 to less than 12, must be experiencing asthma exacerbations and the patient must have baseline IgE levels between 30 and 1300 iu/ml. Patient must have documented evidence of at least 1 perennial aeroallergen (e.g., house dust mite [dermatophagoides farinae, d. Pteronyssinus], animal dander (dog, cat), cockroach, feathers, mold spores) by skin test or in vitro testing. Upon recertification, documentation should be provided validating reduction in asthma exacerbations. Covered for the diagnosis of CHRONIC IDIOPATHIC URTICARIA in patients that have experienced at least a six-month history of urticaria and the presence of hives associated with itching. In addition, the patient must have a documented history of symptomatic failure of H1 antihistamine treatment. Upon recertification, documentation should be provided validating response to therapy (such as decreased severity of itching, decreased size of hives, decreased number of hives). |

| PA Criteria | Criteria Details |
|---|---|
| | Covered for a diagnosis of NASAL POLYPS with documentation of inadequate response to 3-month trial of Xhance nasal spray and inadequate response with Nucala. Recertification will require documentation of continued use of intranasal corticosteroid and clinical benefit from Xolair use (e.g., reduced polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal sxs, improved sense of smell). Covered for the treatment of IgE-MEDIATED FOOD ALLERGY in patients with single or multiple IgE-mediated FAs. Patient must have documented positive skin prick test, allergen-specific IgE, and/or oral food challenge included. Requests will also be evaluated for Part B vs Part D coverage and off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# YONSA

## Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or urologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for a diagnosis of metastatic castration-resistant prostate cancer. In addition, documentation of contraindication to both abiraterone and Xtandi (enzalutamide) must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZOKINVY

## Products Affected

- Zokinvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling |
| **Required Medical Information** | Documentation of diagnosis, pertinent lab/diagnostic test results, and body surface area (BSA) |
| **Age Restrictions** | Patient age must be consistent with the FDA-approval for the stated diagnosis |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a physician knowledgeable in the management of Hutchinson-Gilford Progeria Syndrome and processing-deficient progeroid laminopathies. |
| **Coverage Duration** | Initial approval 6 months. Recertification 1 year. |
| **Other Criteria** | Covered for a diagnosis of Hutchinson Gilford Progeria Syndrome (HGPS) in patients that have heterozygous variant in LMNA gene confirmed by genetic testing and presence of clinical features (e.g., growth deficiency, characteristic facial features, cardiac and neurological issues, musculoskeletal issues). Covered for a diagnosis of processing-deficient progeroid laminopathy in patients with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Recertification will require physician attestation of objective and/or subjective improvement in symptoms compared with baseline condition prior to initiation of Zokinvy therapy. For all diagnoses, BSA must be 0.39 square meters or greater. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZONTIVITY

## Products Affected

- Zontivity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of stroke, transient ischemic attack, or intracranial hemorrhage or current active pathological bleeding (such as intracranial hemorrhage, peptic ulcer bleeding). |
| **Required Medical Information** | Documentation of diagnosis and history of myocardial infarction and/or peripheral arterial disease |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a Cardiologist |
| **Coverage Duration** | One year |
| **Other Criteria** | Zontivity will not be covered for the reduction of cardiovascular events in patients with a history of stroke, transient ischemic attack, intracranial hemorrhage, or active pathological bleeding (such as intracranial or peptic ulcer bleeding). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZTALMY

## Products Affected

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, including supporting labs/diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for the treatment of seizures associated with Cyclin-Dependent Kinase-Like 5 (CDKL5) deficiency disorder confirmed by CDKL5 genetic testing in patients 2 years of age and older. Recertification will require either (1) documentation of a sustained reduction in monthly seizure frequency compared to baseline or (2) subjective or objective evidence from provider that use of Ztalmy has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZURZUVAE

## Products Affected

- Zurzuvae oral capsule 20 mg, 25 mg, 30 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by a psychiatrist, psychiatric nurse practitioner or an obstetrician-gynecologist. |
| **Coverage Duration** | 30 days. |
| **Other Criteria** | Covered for patients with a diagnosis of moderate to severe Postpartum Depression (PPD), based on an ACOG supported validated tool, such as Patient Health Questionnaire-9 (PHQ-9), Hamilton Rating Scale for Depression score (HAMD-17), Edinburgh Postnatal Depression Scale (EPDS). A maximum of 1 treatment course (14 days) will be allowed per a single postpartum period. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- acetylcysteine
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 2.5 mg/0.5 mL
- amphotericin B
- Anzemet oral tablet 50 mg
- aprepitant
- arformoterol
- Astagraf XL
- azathioprine
- budesonide inhalation
- CellCept oral capsule
- CellCept oral tablet
- Clinisol SF 15 %
- cromolyn inhalation
- cyclophosphamide oral
- cyclosporine modified
- cyclosporine oral capsule
- Engerix-B (PF)
- Engerix-B Pediatric (PF)
- Envarsus XR
- everolimus (immunosuppressive)
- formoterol fumarate
- Gengraf
- granisetron HCl oral
- Heplisav-B (PF)
- Humalog U-100 Insulin subcutaneous solution
- Humulin R Regular U-100 Insuln
- Humulin R U-500 (Conc) Insulin
- Imovax Rabies Vaccine (PF)
- insulin lispro subcutaneous solution
- Intralipid intravenous emulsion 20 %, 30 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- Kitabis Pak
- levalbuterol HCl
- Medrol oral tablet 2 mg
- methylprednisolone oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- Myfortic
- Myhibbin
- Neoral oral capsule
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- ondansetron oral tablet,disintegrating 4 mg, 8 mg
- pentamidine inhalation
- prednisolone oral solution
- prednisolone sodium phosphate oral solution 10 mg/5 mL, 20 mg/5 mL (4 mg/mL), 25 mg/5 mL (5 mg/mL), 5 mg base/5 mL (6.7 mg/5 mL)
- Prednisone Intensol
- prednisone oral solution
- prednisone oral tablet
- Prehevbrio (PF)
- Premasol 10 %
- Prograf oral
- Prosol 20 %
- Pulmozyme
- RabAvert (PF)
- Rapamune oral tablet
- Rayos
- Recombivax HB (PF)
- Sandimmune oral
- sirolimus
- tacrolimus oral capsule
- tobramycin in 0.225 % NaCl
- tobramycin inhalation
- Travasol 10 %
- trimethobenzamide oral
- Varubi
- Yupelri

## Details

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

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