**2026 Prior Authorization Requirements**

**Effective 10/01/2026**

# acromegaly therapy

**Products Affected**

- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. Documentation patient has had an inadequate response to surgery or radiation. Current and previous therapies 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** | For the treatment of acromegaly, patients must have had a contraindication, inadequate response, or severe intolerance to/serious side effects from generic injectable octreotide. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# acthar

**Products Affected**

- ACTHAR
- ACTHAR SELFJECT
- 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, inadequate response, or intolerance to/serious side effects (such as steroid-induced mania or sepsis) from 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# actinic keratosis

**Products Affected**

- *diclofenac sodium topical gel 3 %*

| 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 Oncologist |
| **Coverage Duration** | One year. |
| **Other Criteria** | For the treatment of actinic keratoses, patients must have had a contraindication, inadequate response, or severe intolerance to/serious side effects from 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# acute hae

**Products Affected**

- *icatibant*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for the prophylaxis of hereditary angioedema attacks. |
| **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 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# adalimumab

**Products Affected**

- HADLIMA
- HADLIMA (CITRATE-FREE)
- HADLIMA (CITRATE-FREE) PUSHTOUCH
- HADLIMA PUSHTOUCH
- SIMLANDI (CITRATE-FREE) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML, 80 MG/0.8 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 an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year. |

| PA Criteria | Criteria Details |
|---|---|
| **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. Covered for moderate to severe HIDRADENITIS SUPPURATIVA. Covered for moderate to severely active JUVENILE IDIOPATHIC ARTHRITIS (JIA) in pts who have failed to respond to or are intolerant of ONE of the first line agents from the following categories, either alone or in combination for a 3-month period - DMARDs (such as MTX), NSAIDS, analgesics, or corticosteroids. Covered for moderate to severe chronic PLAQUE PSORIASIS that involves at least 3% of their body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 3% BSA if the affected area involves the hands, feet, face, genital region, or scalp. 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 of ONE approved disease-modifying antirheumatic drug (DMARD) agent, 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). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# alpha-1 antitrypsin therapy

**Products Affected**

- PROLASTIN-C INTRAVENOUS SOLUTION

| 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. Request 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | Yes |

# amphetamine

**Products Affected**

- *amphetamine sulfate*
- *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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# apomorphine

**Products Affected**

- *apomorphine*

| 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 neurologist. |
| **Coverage Duration** | One year. |
| **Other Criteria** | 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" and/or unpredictable "on"/"off" episodes. Recertification will require objective and/or subjective evidence from prescriber of a decrease in frequency and/or severity of "wearing-off" and/or unpredictable "on"/"off" episodes. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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, submission of positive sputum culture result obtained after a minimum 6-month treatment with a multi-drug regimen (such as clarithromycin/azithromycin, rifampin, and ethambutol), attestation patient will be using Arikayce in combination with other medications as part of a multi-drug regimen. |
| **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** | Recertification will require documentation of a negative sputum culture while using Arikayce taken within 30 days prior to the recertification 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# attruby

**Products Affected**

- ATTRUBY

| 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). Must present clinical evidence of NYHA class I-III heart failure. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# austedo

**Products Affected**

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 18 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 12-18-24-30 MG

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# behavioral health

**Products Affected**

- *asenapine maleate*
- AUVELITY ORAL TABLET, IR AND ER, BIPHASIC
- AUVELITY ORAL TABLET,IR ER BIPHASIC,DOSEPACK
- BYSANTI
- BYSANTI TITRATION PACK A
- BYSANTI TITRATION PACK B
- BYSANTI TITRATION PACK C
- CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG
- COBENFY ORAL CAPSULE 100-20 MG, 125-30 MG, 50-20 MG
- COBENFY STARTER PACK
- EXXUA ORAL TABLET EXTENDED RELEASE 24 HR
- EXXUA ORAL TABLET, EXT REL 24HR DOSE PACK
- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B
- FANAPT TITRATION PACK C
- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG
- REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG
- SECUADO
- VRAYLAR

| 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 BIPOLAR DISORDER, coverage of asenapine, Bysanti, Caplyta, Fanapt, or Vraylar requires documentation of a contraindication, inadequate response, or severe intolerance to/serious side effects from two generic first-line treatments (such as lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For SCHIZOPHRENIA, coverage of asenapine, Bysanti, Caplyta, Cobenfy, Fanapt, Rexulti, Secuado, or Vraylar requires documentation of a contraindication, inadequate response, or severe intolerance to/serious side effects from two generic first-line treatments (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For MAJOR DEPRESSIVE DISORDER (MDD), coverage of Auvelity, Caplyta, Exxua, Rexulti, or Vraylar requires documentation of inadequate response or severe intolerance to/serious side effects from TWO generic first-line treatments indicated for MDD (such as SSRIs, SNRIs, bupropion, mirtazapine). Coverage of Opipza Oral Film requires documentation that aripiprazole oral solution, oral tablets OR oral disintegrating tablets are not appropriate or contraindicated for the patient. Auvelity and Rexulti covered for AGITATION ASSOCIATED WITH DEMENTIA DUE TO ALZHEIMER DISEASE. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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. Attestation that patient is currently using standard therapy to treat diagnosis and that such standard therapy will be continued after Benlysta is started. Standard therapy is defined consistent with current recommended clinical practice as hydroxychloroquine (unless contraindicated), and possibly immunosuppressive agents such as azathioprine, mycophenolate mofetil, methotrexate, tacrolimus, cyclosporine, or cyclophosphamide added with or without corticosteroids to control inflammation and prevent organ damage. |
| **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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# besremi

**Products Affected**

- BESREMI
- BESREMI PEN

| 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. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# bexarotene gel

**Products Affected**

- *bexarotene topical*

| 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BOTOX

**Products Affected**

- BOTOX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Excluded for cosmetic uses. |
| **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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BRAF/MEK

**Products Affected**

- BRAFTOVI
- COTELLIC
- MEKINIST
- MEKTOVI
- TAFINLAR
- ZELBORAF

| 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# brinsupri

**Products Affected**

- BRINSUPRI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis of non-cystic fibrosis bronchiectasis (NCFB), confirmed (or documented) by high-resolution chest CT scan. |
| **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 pulmonologist or infectious disease specialist experienced in treating bronchiectasis. |
| **Coverage Duration** | One year. |
| **Other Criteria** | There must be a documented history of at least 2 pulmonary exacerbations in the past 12 months requiring systemic antibiotics OR at least 1 exacerbation requiring hospitalization/IV antibiotics.Recertification requires documentation of or provider attestation of clinical benefit (i.e., a reduction in pulmonary exacerbations, improved 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BTKi

**Products Affected**

- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET
- CALQUENCE
- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG
- JAYPIRCA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. For Brukinsa for marginal zone lymphoma, submission of previous antiCD20-based regimen/s. For Brukinsa for follicular lymphoma, submission of at least two lines of previous systemic therapy. For Brukinsa or Calquence for mantle cell lymphoma, submission of prior therapy or therapies used, if any. For Imbruvica for chronic graft-versus-host disease, submission of prior therapy or therapies tried and failed. |
| **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 Brukinsa/zanubrutinib requires intolerance or contraindication to Calquence/acalabrutinib OR Imbruvica/ibrutinib. NOTE: for treatment of Waldenstrom's Macroglobulinemia, step through another BTKi drug is not required before approval of Brukinsa/zanubrutinib. For shared indications, Jaypirca/pirtobrutinib requires a trial with Calquence/acalabrutinib OR Imbruvica/ibrutinib. Coverage of Imbruvica 140 mg and 280mg TABLETS requires documented inability to use Imbruvica CAPSULES used to achieve equivalent 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# budesonide foam

**Products Affected**

- *budesonide rectal*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. As topical budesonide does not have proven efficacy to maintain remission, chronic therapy with budesonide foam will not be authorized. |
| **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** | For the treatment of ulcerative colitis, the patient must have had a contraindication, inadequate response, or severe intolerance to/serious side effects from topical mesalamine (enemas or suppositories), or hydrocortisone enemas. 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 be approved in 6-week intervals. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# bylvay

**Products Affected**

- BYLVAY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Clinical evidence of decompensated cirrhosis and 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 pruritus due to progressive familial intrahepatic cholestasis (PFIC). Recertification for both indications requires documentation that the patient is tolerating therapy and is experiencing a decrease in pruritus 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# cablivi

**Products Affected**

- CABLIVI INJECTION KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, attestation patient will continue to receive plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab) while using Cablivi. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# CDK 4/6

**Products Affected**

- IBRANCE
- KISQALI
- KISQALI FEMARA CO-PACK ORAL TABLET 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG
- VERZENIO

| 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 oncologist or hematologist. |
| **Coverage Duration** | One year. |
| **Other Criteria** | For shared indications, coverage of Verzenio/abemaciclib requires intolerance or contraindication to Ibrance/palbociclib OR 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# cgrp antagonists

**Products Affected**

- AIMOVIG 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** | None |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | For episodic or chronic migraine headache,patient must have tried and failed two different classes of medications supported by compendia for the prophylactic treatment of migraine headache (such as amitriptyline, divalproex sodium, propranolol, timolol, topiramate, or venlafaxine). Eight-week trials of each of the two medications is required unless intolerance was the reason for clinical failure. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CHORIONIC GONADOTROPIN

**Products Affected**

- *chorionic gonadotropin, human intramuscular*
- PREGNYL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used to promote fertility. |
| **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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CLOMIPHENE

**Products Affected**

- *clomiphene citrate*
- MILOPHENE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded when used to promote fertility. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 3% body surface area (BSA). Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with psoriasis that involves less than 3% BSA if the affected area involves the hands, feet, scalp, 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 indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | Yes |

# cuvrior

**Products Affected**

- CUVRIOR

| 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# deflazacort

**Products Affected**

- *deflazacort oral suspension*
- *deflazacort 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# dichlorphenamide

**Products Affected**

- *dichlorphenamide*
- 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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 molecularly confirmed long-chain fatty acid oxidation disorders. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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. |
| **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 a corticosteroid or immunoglobulin therapy (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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# dronabinol

**Products Affected**

- *dronabinol oral capsule*

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# dupixent

**Products Affected**

- DUPIXENT SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML
- DUPIXENT SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. Not indicated for other forms of urticaria other than chronic spontaneous urticaria (CSU). |
| **Required Medical Information** | Diagnosis. For all submissions of previous therapies used, see Other Criteria. For MODERATE-TO-SEVERE EOSINOPHILIC ASTHMA: (1) either (a) blood eos count at least 150 cells/mcL obtained w/in 6 wks of therapy initiation OR (b) evidence of daily oral steroid dependence and (2) adults with pre-bronchodilator FEV1 less than 80% predicted and (3) previous therapies used. BULLOUS PEMPHIGOID (BP) confirmed by histopathological and direct immunofluorescence (DIF) c/w BP. If no histopath/DIF findings c/w BP, evidence other diagnostics supportive of BP must be provided (e.g., ELIZA, IgG BMZ deposition, indirect immunofluorescence). For COPD: (1) either (a) blood eos count of at least 300 cells/mcL obtained within 6 wks of therapy initiation OR (b) evidence of daily oral steroid dependence and (2) post-bronchodilator FEV1/FVC ratio less than 0.7 and post-bronchodilator FEV1 of 30% to 80% predicted and (3) current therapies. For MOD TO SEVERE ATOPIC DERMATITIS: diagnosis and previous tx used. For CRSwNP: previous tx used. For CHRONIC SPONTANEOUS URTICARIA: (1) at least consecutive 6 wks of symptoms (hives, itching, and/or angioedema) and (2) previous tx used. For EOSINOPHILIC ESOPHAGITIS: (1) dx confirmed by upper endoscopy w/biopsy showing at least 15 eos/high-power field or 60 eos/mm2 and (2) clinical sxs such as difficulty swallowing, food impaction (stuck in the esophagus), acid reflux, N/V, abdominal or chest pain and (3) provider attestation other causes have been ruled out (including, but not limited to GERD, HES, EGPA) and (4) previous tx used. For PRURIGO NODULARIS: (1) pruritus lasting at least 6 wks, (2) signs of repeated scratching, picking, or rubbing (e.g., excoriations and scars), and (3) presence of multiple pruriginous, firm, nodular lesions. For ALLERGIC FUNGAL RHINOSINUSITIS (AFRS): diagnosis supported by clinical documentation (e.g. CT findings, pathology reports, history of surgery, fungal sensitization). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **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 |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For COPD: unless there is a documented intolerance or contraindication to one or more components, patient must have at least a 3-month trial of triple therapy consisting of a long-acting muscarinic antagonist, long-acting beta agonist, and inhaled corticosteroid (such as Breztri or Trelegy or by using a combination of products containing these MOA ingredients). For ASTHMA and COPD: Must be used as add-on therapy to existing maintenance therapy. For ATOPIC DERMATITIS: documentation patient is refractory to at least ONE topical therapy. Covered for BULLOUS PEMPHIGOID (BP) with a TWO-week trial of ONE of the following: 1) high-potency topical steroid, 2) oral steroids 3) a tetracycline antibiotic (though not required, doxycycline is preferred based on safety, efficacy, and availability), OR 4) mycophenolate mofetil. For CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: documentation of (1) inadequate response to 8-week trial of an intranasal corticosteroid approved for nasal polyps AND (2) trial of oral steroids in past 6 months OR prior sinus surgery in past 2 years. 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 symptoms, improved sense of smell). For CHRONIC SPONTANEOUS URTICARIA: patient must have continued symptoms despite an adequate trial (minimum of four weeks) of a second-generation H1-antihistamine at highest tolerated dose up to 2-4 times the standard dose. For EOSINOPHILIC ESOPHAGITIS: documentation of serious side effects or drug failure with oral liquid steroids (e.g., fluticasone or budesonide) plus a proton pump inhibitor at highest tolerated dose up to twice-daily dosing for at least 8 weeks. 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 (pruritus) and clearer skin (less firm nodular lesions) from baseline/initial request. For AFRS: prior sinonasal surgery with documented persistent or recurrent disease despite a trial of post-op medical management (either intranasal and/or systemic steroids). Recertification will require documented clinical benefit from Dupixent use (e.g., reduced polyp size, improved nasal congestion or sense of smell, decreased systemic steroid use, or avoidance of repeat sinonasal surgery). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | For all shared indications, patient must try ONE formulary adalimumab biosimilar (Hadlima or Simlandi) before approval of Enbrel. If contraindication to Hadlima AND Simlandi, then a trial with one of these is not required before approval of Enbrel. Enbrel will also be approved for patients with documented inadequate response after a trial with any previous adalimumab product. Enbrel is covered without additional step through formulary adalimumabs for all FDA approved indications of Enbrel not shared by Hadlima and Simlandi. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# endari

**Products Affected**

- *glutamine (sickle cell)*

| 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 reducing the acute complications of sickle cell disease, including symptomatic pain relief. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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 1 Neuromyelitis Optica relapse that required rescue therapy (such as corticosteroids or plasma exchange) in 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 as confirmed by elevated prostate-specific antigen (PSA) test and any one of the following: biopsy, imaging study or lab diagnostic test such as 4Kscore Test or Prostate Health Index (PHI). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# esrd

**Products Affected**

- PROCRIT
- 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# evenity

**Products Affected**

- EVENITY

| 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 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# evrysdi

**Products Affected**

- EVRYSDI ORAL RECON SOLN
- EVRYSDI ORAL TABLET

| 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 provider attestation of improvement or slowing of disease progression attributed to the use of Evrysdi. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# gabapentin ER

**Products Affected**

- *gabapentin 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 intolerance or contraindication to generic immediate-release gabapentin. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GLP-1 Agonists

**Products Affected**

- OZEMPIC
- RYBELSUS
- TRULICITY

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# gonadotropin releasing hormone analogs

**Products Affected**

- *leuprolide subcutaneous 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** | One year. |
| **Other Criteria** | Covered for treatment of advanced prostate cancer, defined as stage III or stage IV. Requests will also be evaluated for off-label use. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# growth hormone

**Products Affected**

- OMNITROPE

| 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. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist, pediatric endocrinologist, nephrologist, infectious disease specialist, or gastroenterologist. |
| **Coverage Duration** | One year |

| PA Criteria | Criteria Details |
|---|---|
| **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. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Impavido

**Products Affected**

- IMPAVIDO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pregnancy or 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 or recommended by an infectious disease specialist. |
| **Coverage Duration** | 28 days. |
| **Other Criteria** | Covered for the treatment of visceral (caused by Leishmania donovani), cutaneous (caused by L. braziliensis, L. guyanensis, and L. panamensis), and mucosal leishmaniasis (caused by L. braziliensis) in patients weighing at least 30 kg. Efficacy of Impavido in the treatment of other Leishmania species has not been evaluated and therefore not covered. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ingrezza

**Products Affected**

- INGREZZA INITIATION PACK
- 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INJECTABLE ONCOLOGY

**Products Affected**

- ELREXFIO
- PHESGO

| 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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# isturisa

**Products Affected**

- ISTURISA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **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** | One year. |
| **Other Criteria** | Covered for the treatment of endogenous hypercortisolemia in adults with Cushing syndrome 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. In those patients with Cushing Disease (Cushing Syndrome that is caused by a pituitary adenoma ), there must also be intolerance 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 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 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, 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** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ivig

**Products Affected**

- GAMMAGARD LIQUID
- GAMMAGARD LIQUID ERC
- GAMMAKED
- GAMUNEX-C
- OCTAGAM
- 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. For immune thrombocytopenic purpura (ITP), submission of platelet count with the requirement with a requirement it is less than 30,000/mcL or less than 50,000/mcL with documented increased risk of bleeding. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Journavx

**Products Affected**

- JOURNAVX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Will not be covered for treatment of chronic pain (defined as pain lasting one month duration or greater). |
| **Required Medical Information** | Diagnosis. |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Covered for patients with a diagnosis of moderate to severe acute pain. Acute pain is classified as pain less than one month duration and is usually sudden, time-limited, and caused by injury, trauma, or treatments such as surgery. Subsequent reviews must be for a new moderate to severe acute pain or injury. Repeat treatment for the same injury or acute pain condition will not be authorized. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# juxtapid

**Products Affected**

- JUXTAPID ORAL CAPSULE 10 MG, 2 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** | Covered for the diagnosis of homozygous familial hypercholesterolemia (HoFH), as adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol, apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C). For individuals 10 years of age and older, the patient must have a baseline LDL of at least 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 also required. For individuals age 2 to 9 years old, the patient must have a baseline LDL of at least 130 while receiving lipoprotein apheresis. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# kerendia

**Products Affected**

- KERENDIA

| 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 chronic kidney disease associated with type 2 diabetes in patients with inadequate response, intolerance, or contraindication to an ACE-I or ARB. Covered for heart failure with left ventricular ejection fraction greater than or equal to 40% in patients with inadequate response, intolerance, or contraindication to an ACE-I or ARB AND an SGLT2. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# kineret

**Products Affected**

- KINERET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent lab/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 the treatment of moderate to severe RHEUMATOID ARTHRITIS for patients with documented failure to TWO of the following alternatives: Hadlima, Orencia, Rinvoq, Simlandi, 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# lidocaine patch

**Products Affected**

- *lidocaine topical adhesive patch,medicated 5 %*

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# livmarli

**Products Affected**

- LIVMARLI ORAL SOLUTION
- LIVMARLI ORAL TABLET 10 MG, 15 MG, 20 MG, 30 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Genetic testing confirming Alagille Syndrome (ALGS) or progressive familial intrahepatic cholestasis (PFIC) is required. Note: per FDA-approved prescribing information, Livmarli is not recommended 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. Therefore, Livmarli will not be approved for this subgroup of patients. 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. |
| **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 ALGS or PFIC. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |
| **Other Criteria** | Covered for treatment of cholestatic pruritus in patients with genetic testing confirmed ALGS. Covered for treatment of cholestatic pruritus with 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# Lybalvi

**Products Affected**

- LYBALVI ORAL TABLET 10-10 MG, 15-10 MG, 20-10 MG, 5-10 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 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** | Must be prescribed by a neurologist or psychiatrist. |
| **Coverage Duration** | One year. |
| **Other Criteria** | Coverage 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, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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). Mavyret 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# memantine-donepezil

**Products Affected**

- *memantine-donepezil*

| 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** | Memantine-donepezil 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# mifepristone

**Products Affected**

- *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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# migraine other

**Products Affected**

- NURTEC ODT

| 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 headache or pain specialist or neurologist |
| **Coverage Duration** | One year. |
| **Other Criteria** | For the acute treatment of migraine headache with or without aura, Nurtec is covered with documentation of trial and failure or severe intolerance to one generic triptan product. Covered for episodic or chronic migraine headache. Recertification for either indication will require documentation that the drug continues to effectively reduce frequency, duration, and/or severity of 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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 and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients weighing at least 50 kg. In addition, there must be documentation of severe intolerance, contraindication to or the 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# nitisinone

**Products Affected**

- HARLIKU
- *nitisinone*
- NITYR

| 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 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** | Nitisinone capsules and Nityr tablets are 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 contraindication of the preferred product generic nitisinone capsules. Harliku tablets are covered for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU). Diagnosis must be confirmed by an elevated urinary HGA excretion and HGC plasma concentration at baseline. Recertification requires documentation of improvement from baseline(s) OR sustained clinical benefits. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# nuedexta

**Products Affected**

- *dextromethorphan-quinidine*
- 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ofev

**Products Affected**

- *nintedanib*
- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Computed tomography (CT) scan report, pulmonary function test (PFT) showing FVC values, documentation of previous & current therapies. |
| **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). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# onychomycosis

**Products Affected**

- *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 trichophyton 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# opioid-induced constipation

**Products Affected**

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE 12 MG/0.6 ML, 8 MG/0.4 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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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. 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. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | Yes |

# oral oncology

**Products Affected**

- *abiraterone oral tablet 250 mg*
- AKEEGA
- ALECENSA
- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK
- AUGTYRO ORAL CAPSULE 160 MG, 40 MG
- AVMAPKI-FAKZYNJA
- AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG
- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG
- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG
- *bosutinib oral tablet 100 mg, 400 mg, 500 mg*
- CABOMETYX
- CAPRELSA ORAL TABLET 100 MG, 300 MG
- CAVHANZA
- COMETRIQ
- COPIKTRA
- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*
- DAURISMO ORAL TABLET 100 MG, 25 MG
- ENSACOVE
- ERIVEDGE
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet for suspension 2 mg, 3 mg, 5 mg*
- FOTIVDA
- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG
- GAVRETO
- *gefitinib*
- GILOTRIF
- GOMEKLI
- HERNEXEOS
- HYRNUO
- IBTROZI
- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG
- IDHIFA
- *imatinib oral tablet 100 mg, 400 mg*
- IMKELDI
- INLURIYO
- INLYTA ORAL TABLET 1 MG, 5 MG
- INQOVI
- INREBIC
- ITOVEBI ORAL TABLET 3 MG, 9 MG
- IWILFIN
- JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG
- JIDEYTRO ORAL TABLET 100 MG, 25 MG
- KOMZIFTI
- KOSELUGO
- KRAZATI
- *lapatinib*
- LAZCLUZE ORAL TABLET 240 MG, 80 MG
- *lenalidomide*
- 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)
- LIFYORLI
- 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)
- MODEYSO
- NERLYNX
- *nilotinib hcl*
- NINLARO
- NUBEQA
- ODOMZO
- OGSIVEO ORAL TABLET 100 MG, 150 MG
- OJEMDA
- OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG
- ONUREG
- ORSERDU ORAL TABLET 345 MG, 86 MG
- *pazopanib oral tablet 200 mg, 400 mg*
- PEMAZYRE
- PIQRAY
- *pomalidomide*
- POMALYST
- QINLOCK
- RETEVMO ORAL TABLET
- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG
- REZLIDHIA
- ROMVIMZA
- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET
- RUBRACA
- RYDAPT

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG
- *sorafenib*
- STIVARGA
- *sunitinib malate*
- TABRECTA
- TAGRISSO
- TALZENNA
- TASIGNA
- TAZVERIK
- TEPMETKO
- TIBSOVO
- TRUQAP
- TUKYSA ORAL TABLET 150 MG, 50 MG
- TURALIO
- VANFLYTA
- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK
- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION
- VIZIMPRO
- VONJO
- VORANIGO ORAL TABLET 10 MG, 40 MG
- XALKORI
- XOSPATA
- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (10 MG X 4), 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), 80 MG/WEEK (80 MG X 1), 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
- ZOLINZA
- ZYDELIG
- ZYKADIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition. |
| **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. Renewal criteria: documentation that disease progression has not occurred. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# orencia

**Products Affected**

- ORENCIA (WITH MALTOSE)
- 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. For acute graft versus host disease, documentation patient is undergoing hematopoietic stem cell transplantation . |
| **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. Request 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. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# orgovyx

**Products Affected**

- ORGOVYX

| 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 oncologist, hematologist or for prostate cancer, a urologist. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# otezla

**Products Affected**

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20 MG (51), 10 MG (4)-20 MG (4)-30 MG (47)
- OTEZLA XR
- OTEZLA XR INITIATION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, BSA if for psoriasis, 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 as treatment for adults with PLAQUE PSORIASIS who are candidates for phototherapy or systemic therapy and treatment of pediatric patients at least 6 years of age and at least 20 kg (immediate release) or at least 50 kg (extended release) with moderate to severe plaque psoriasis (BSA of at least 3%) who are candidates for phototherapy or systemic therapy. BSA of at least 3% is not required if the affected area involves the hands, feet, scalp, 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# oxervate

**Products Affected**

- OXERVATE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, pertinent diagnostic test results (such as corneal sensitivity testing or slit-lamp examination), and 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** | Approval is for 8 weeks. Retreatment courses will not be approved. |
| **Other Criteria** | Must have a diagnosis of stage 2 (persistent epithelial defect, PED) or stage 3 (corneal ulcer) neurotrophic keratitis (NK). Must have failed treatment with one or more conventional treatments for NK such as preservative-free ophthalmic lubricants (artificial tears, gel, or ointment). Clear progress note documentation of inadequate response with at least two different OTC lubricants must be provided as there will be no pharmacy claim history of OTC products. Evidence must be provided that toxic or preservative-containing ophthalmic drugs have been evaluated for appropriateness of discontinuation, to the extent that they may contribute to NK. Retreatment courses will not be approved as there have been no studies to document the efficacy of treatment beyond a single 8-week course. Quantity limit is 56 mL per 365 days to allow for 8 weeks of treatment in one eye. If there is documentation of a need for treatment in both eyes, a quantity limit of 112 mL per 365 days will be granted. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# pirfenidone

**Products Affected**

- *pirfenidone oral capsule*

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# procysbi

**Products Affected**

- PROCYSBI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Hypersensitivity to penicillamine 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# promacta

**Products Affected**

- *eltrombopag olamine oral powder in packet 12.5 mg, 25 mg*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*
- 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. 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 or persistent immune thrombocytopenia purpura (ITP) in patients who have experienced an insufficient response to previous treatment with either ONE of the following: corticosteroids or immunoglobulins (IVIG). Insufficient response is defined as a platelet count of less than 30,000/microliter OR at least 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** | |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# prophylactic hae

**Products Affected**

- HAEGARDA
- 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. |
| **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 non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# pulmonary hypertension

**Products Affected**

- ADEMPAS
- *ambrisentan oral tablet 10 mg, 5 mg*
- *bosentan oral tablet 125 mg, 62.5 mg*
- *macitentan*
- OPSUMIT
- OPSYNVI
- ORENITRAM
- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- *sildenafil (pulmonary hypertension) oral tablet*
- *tadalafil (pulmonary hypertension)*
- UPTRAVI ORAL TABLET 1,000 MCG, 1,200 MCG, 1,400 MCG, 1,600 MCG, 100 MCG, 150 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI ORAL TABLETS,DOSE PACK
- WINREVAIR
- YUTREPIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis, right heart catheterization results if PAH |
| **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** | Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, coverage of Adempas, Orenitram, Uptravi, and Yutrepia for PAH require trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan). Adempas covered for chronic thromboembolic pulmonary hypertension (CTEPH). Opsumit, macitentan, and Opsynvi require a trial with a generic ERA (ambrisentan, bosentan). Winrevair requires at least 3-month trial with at least two standards of care advanced therapies from two different classes (such as PDE5 inhibitor, ERA, soluble guanylate cyclase stimulator (sGC), prostacyclin receptor agonist, prostacyclin). Recertification requires objective and/or subjective clinical evidence of disease improvement attributed to use of approved drug(s). 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | Yes |

# 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) improvement in hemoglobin level 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# radicava

**Products Affected**

- RADICAVA ORS STARTER KIT SUSPENSION

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | One 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# revcovi

**Products Affected**

- REVCOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Must not have severe thrombocytopenia (considered to be a platelet count of below 50,000 cells/microliter). |
| **Required Medical Information** | Diagnosis confirmed by one of the following (1 or 2): 1) Absent or very low (less than 1 percent of normal) adenosine deaminase (ADA) catalytic activity in 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. Documentation of elevated deoxyadenosine triphosphate (dATP) levels or total deoxyadenosine (dAdo) nucleotides in erythrocytes (red blood cells) compared to a laboratory standard. Current body weight and thrombocyte count. |
| **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 a physician that specializes in the treatment of ADA-SCID. |
| **Coverage Duration** | One year |
| **Other Criteria** | Patient must not be a suitable candidate for hematopoietic cell transplantation (HCT) at the time of the request OR have already failed HCT. Recertification requires documentation of a favorable response to treatment such as one or more of the following: a. Improvement in immune status relative to baseline before treatment (total lymphocyte and B, T, and natural killer (NK) lymphocyte counts, quantitative immunoglobulin (Ig) concentration [IgG, IgA, IgM]), b. Improvement in clinical status relative to baseline before treatment (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. 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | No |

# rezdiffra

**Products Affected**

- REZDIFFRA ORAL TABLET 100 MG, 60 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Decompensated cirrhosis and as limited by FDA labeling. |
| **Required Medical Information** | Pertinent lab and diagnostic imaging results. Prescriber attestation patient has been counseled on comprehensive lifestyle modification (i.e., nutrition, exercise, reduced alcohol consumption, and behavior modification) and documentation that comorbid metabolic conditions are being treated including current therapies used as standard of care (i.e., current therapy for hypertension or hypertriglyceridemia if that is the metabolic condition in patient). |
| **Age Restrictions** | Patient age must be consistent with the FDA approval for the stated diagnosis. |
| **Prescriber Restrictions** | Must be prescribed by an endocrinologist, gastroenterologist, or hepatologist. |
| **Coverage Duration** | One year. |
| **Other Criteria** | Covered for the diagnosis of non-cirrhotic metabolic dysfunction associated steatotic liver disease (MASLD) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Diagnosis must be confirmed by one of the following: (1) serum biomarkers (i.e., FIB-4 index, NAFLD fibrosis score, ELF test) AND an imaging biomarker such as Elastography [examples include, but are not limited to, vibration-controlled transient elastography (VCTE) {e.g., FibroScan}, transient elastography (TE), magnetic resonance elastography (MRE), acoustic radiation force impulse (ARFI) imaging, shear wave elastography (SWE), magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF)] OR (2) liver biopsy showing non-alcoholic fatty liver disease activity score of 4 or greater with a score of 1 or greater in ALL of the following: steatosis, ballooning AND lobular inflammation. Documentation or provider attestation required that the patient has at least ONE of the following metabolic risk factors that are managed according to standard of care: central obesity, hypertension, hypertriglyceridemia, low HDL cholesterol, elevated fasting plasma glucose. Recertification requires stable or improving noninvasive liver disease assessment (NILDA), improvement in liver stiffness measure OR subjective or objective evidence from provider that use of Rezdiffra 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** | |

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

# REZUROCK

**Products Affected**

- REZUROCK

| 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 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. If ibrutinib is contraindicated, then a trial of at least 2 therapies is required prior to Rezurock for cGVHD. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# rinvoq

**Products Affected**

- RINVOQ LQ
- 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. 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Covered for ANKYLOSING SPONDYLITIS (AS) in pts who have had serious side effects or drug failure w/ ONE of: Hadlima or Simlandi. 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 moderate to severe CROHN'S DISEASE (CD) in patients who meet ONE of the following conditions: (1) Previous TNF-blocker use: a) the patient has experienced intolerable adverse effects or inadequate response to Hadlima or Simlandi, OR b) patient has trialed another TNF-blocker indicated for CD and experienced intolerable adverse effects or inadequate response OR (2) if TNF-blocker therapy is contraindicated or clinically inappropriate, the patient must have received at least one approved systemic therapy for CD prior to initiating this medication. Covered for a diagnosis of GIANT CELL ARTERITIS. Covered for the diagnosis of NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS. Covered for PSORIATIC ARTHRITIS (PsA) in pts who have had serious side effects or drug failure with ONE of: Hadlima or Simlandi. 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 ONE of: Hadlima or Simlandi. TNF-blocker-experienced patients must have had serious side effects or drug failure with any RA-indicated TNF-blocker. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in patients who have had inadequate response or intolerance with at least ONE TNF-blocker. If TNF-blocker therapy is contraindicated or clinically inappropriate, the patient must have received at least one approved systemic therapy for UC. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# SCIG

**Products Affected**

- HIZENTRA
- HYQVIA

| 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** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | One 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 (see Other Criteria) |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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 Friedreichs 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 Friedreichs ataxia (FA). |
| **Coverage Duration** | One year |
| **Other Criteria** | Covered for patients with a diagnosis of Friedreichs 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 Friedreichs 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# skyrizi

**Products Affected**

- SKYRIZI SUBCUTANEOUS PEN INJECTOR MG/2.4 ML (150 MG/ML)
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 55 MG/0.37 ML
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360

| 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 moderately to severely active CROHN's DISEASE. Covered for patients with a diagnosis of moderate to severe chronic PLAQUE PSORIASIS that involves at least 3% body surface area. Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 3% BSA if the affected area involves the hands, feet, facial, scalp, 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 Psoralen Ultraviolet A (PUVA) Phototherapy for at least 3 months OR 3) have tried and failed (a) treatment with medium and/or high potency topical corticosteroids for at least 1 month AND (b) ONE of these for at least 3 months: anthralin, calcipotriene, or tazarotene. Covered for the treatment of active PSORIATIC ARTHRITIS. Covered for the diagnosis of moderately to severely ULCERATIVE COLITIS. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# sleep disorders

**Products Affected**

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*
- SUNOSI ORAL TABLET 150 MG, 75 MG

| 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 is 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# sodium oxybate

**Products Affected**

- *sodium oxybate*

| 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. |
| **Coverage Duration** | One year. |
| **Other Criteria** | Covered for a diagnosis of cataplexy associated with narcolepsy. Covered for the treatment of excessive daytime sleepiness associated with narcolepsy without cataplexy in pediatric patients less than 18 years of age. Covered for the treatment of excessive daytime sleepiness associated with narcolepsy without cataplexy in adults that have failed or had an intolerance to both armodafinil AND modafinil. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# Spiriva Respimat

**Products Affected**

- SPIRIVA RESPIMAT

| 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 CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) in patients who have had an inadequate response or contraindication to both Incruse Ellipta and Spiriva Handihaler. Covered for a diagnosis of MODERATE TO SEVERE ASTHMA as add-on maintenance therapy. Patient must have had drug failure (inadequate or poor asthma symptom control) with at least 3 months of optimal maintenance therapy. Maintenance therapy is defined as an inhaled steroid in combination with a long-acting beta agonist (ICS-LABA) or ICS in combination with a leukotriene inhibitor or theophylline. Recertification for asthma requires documentation of continued use of ICS-LABA (or other maintenance therapy) and clinical benefit from Spiriva Respimat use (such as reduced asthma exacerbations, less use of rescue inhaler). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# tadalafil for daily use

**Products Affected**

- *tadalafil oral tablet 2.5 mg, 5 mg (generic for cialis)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tadalafil for daily use is excluded for the independent diagnosis of Erectile Dysfunction. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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). Must present clinical evidence of NYHA class I-III heart failure. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 proteinuria (defined as greater than or equal to 0.5 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# tasimelteon

**Products Affected**

- *tasimelteon*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **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** | 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 tasimelteon capsules will only be approved in patients with non-24 who are totally blind. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# teriparatide

**Products Affected**

- *teriparatide*

| 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 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** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# thalomid

**Products Affected**

- THALOMID ORAL CAPSULE 100 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# tocilizumab

**Products Affected**

- TYENNE AUTOINJECTOR
- TYENNE 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 all FDA approved and medically accepted indications with documented inadequate response to ONE preferred product (such as Hadlima, Simlandi, or Rinvoq). Trialed preferred product must share the FDA or medically accepted indication for which current drug is being requested. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# tolvaptan

**Products Affected**

- *tolvaptan (polycys kidney dis) oral tablet 15 mg, 30 mg*
- *tolvaptan (polycys kidney dis) oral tablets, sequential 15 mg (am)/ 15 mg (pm), 30 mg (am)/ 15 mg (pm), 45 mg (am)/ 15 mg (pm), 60 mg (am)/ 30 mg (pm), 90 mg (am)/ 30 mg (pm)*

| 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 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 3 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# topical retinoids

**Products Affected**

- *adapalene topical cream*
- *adapalene topical gel 0.3 %*
- ALTRENO
- ARAZLO
- FABIOR
- *tazarotene*
- *tretinoin*
- TRILITAS

| 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, and tretinoin products will be approved for the diagnosis of acne vulgaris. In addition, tazarotene 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Trikafta

**Products Affected**

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

| 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 or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TRIPTODUR

**Products Affected**

- TRIPTODUR

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Tyvaso Inhalation

**Products Affected**

- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. For PAH and PAH-ILD: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest and Pulmonary Vascular Resistance (PVR) greater than 2 wood units (WU). For PAH-ILD, also require baseline PFT results confirming moderate to severely impaired lung disease including FVC less than 70%, AND high-resolution CT scan finding characteristic airway and/or parenchymal abnormalities associated with interstitial lung disease AND baseline 6-minute walk test to assess disease severity and clinical response to treatment, AND baseline NT-proBNP [N-terminal pro-B-type natriuretic peptide] level. |
| **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** | For PULMONARY ARTERIAL HYPERTENSION (PAH): coverage of Tyvaso inhalation solution requires a trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan). Recertification requires objective and/or subjective clinical evidence of disease improvement attributed to use of approved drug(s). Also covered for the treatment of PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (WHO Group 3) to improve exercise ability. Must have clinical symptoms associated with PH-ILD such as shortness of breath with exertion that is not fully explained by the severity of lung disease, decreased exercise capacity, labored breathing, fatigue, lethargy. Recertification will require documentation of stabilization or improvement in 6MWT from baseline, decrease in NT-proBNP levels as well as stabilization or reduction in disease severity such as improvements in FVC, reduction in exacerbations of the underling lung disease and clinical worsening. 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ursodiol

**Products Affected**

- *ursodiol oral capsule 200 mg, 400 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 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ustekinumab

**Products Affected**

- SELARSDI SUBCUTANEOUS SOLUTION
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- *ustekinumab subcutaneous solution*
- *ustekinumab subcutaneous syringe 45 mg/0.5 ml, 90 mg/ml*
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 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 an appropriate specialist to treat the stated diagnosis. |
| **Coverage Duration** | One year. |
| **Other Criteria** | For Selarsdi and Yesintek: Covered for a diagnosis of moderate to severe active CROHN'S DISEASE. Covered for patients with a diagnosis of moderate to severe chronic PLAQUE PSORIASIS that involves at least 3% body surface area. Covered for the diagnosis of moderate to severe chronic PLAQUE PSORIASIS in patients with less than 3% BSA if the affected area involves the hands, feet, facial, scalp 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 Psoralen Ultraviolet A (PUVA) Phototherapy for at least 3 months OR 3) have tried and failed (a) treatment with medium and/or high potency topical corticosteroids for at least 1 month AND (b) ONE of these for at least 3 months: anthralin, calcipotriene, or tazarotene. Covered for the diagnosis of PSORIATIC ARTHRITIS. Covered for the diagnosis of moderately to severely active ULCERATIVE COLITIS. For Stelara & ustekinumab (unbranded Stelara): covered for patients who have a contraindication or inability to use one of the preferred biosimilars, Selarsdi or Yesintek. DOSING: 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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/or previous skin-directed therapy. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# veppanu

**Products Affected**

- VEPPANU ORAL TABLET 100 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** | Must be prescribed by, or in consultation with, an oncologist. |
| **Coverage Duration** | One year. |
| **Other Criteria** | Covered for patients that has all 3: (1) a diagnosis of estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-), ESR1-mutated recurrent unresectable or metastatic breast cancer (mBC) AND (2) has progressed following standard first-line therapy with at least one line of endocrine therapy and a CDK 4/6 inhibitor in the metastatic setting AND (3) hasn't progressed on treatment with another selective estrogen receptor degrader (SERD). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# verkazia

**Products Affected**

- VERKAZIA

| 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 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 or Alocril). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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 such as but not limited to: echocardiograph results, ECG, chest X-ray, cardiac MRI, or labs (such as BNP or NT-proBNP) to support the heart failure 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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# voriconazole (IV)

**Products Affected**

- *voriconazole intravenous recon soln*
- *voriconazole-hpbcd*

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# vowst

**Products Affected**

- VOWST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Must have a stool test positive for toxigenic Clostridioides difficile within the past 30 days. |
| **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 gastroenterologist or infectious diseases specialist. |
| **Coverage Duration** | One month. |
| **Other Criteria** | Covered for prevention of Clostridioides difficile infection (CDI) in patients who have had at least 2 recurrent episodes of CDI. Must have completed an antibiotic course for the treatment of CDI two to four days before initiation of treatment with Vowst. Patient must not be immune compromised. Retreatment with Vowst for the same CDI will not be covered. Vowst will not be covered for the treatment of active CDI. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# vyvgart hytrulo PFS

**Products Affected**

- VYVGART HYTRULO SUBCUTANEOUS SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | All diagnoses require previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy. For chronic inflammatory demyelinating polyneuropathy (CIDP): documentation of confirmed diagnosis by electrodiagnostic testing (e.g., electromyography (EMG), nerve conduction studies (NCS)), MRI, or nerve biopsy. Documentation of baseline score on an objective scale to assess clinical response (e.g., Rankin, Modified Rankin, Medical Research Council (MRC), Inflammatory Rasch-built Overall Disability Scale (I-RODS), Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale). For Generalized Myasthenia Gravis (gMG): Myasthenia Gravis Foundation of America (MGFA) clinical classification, MG activities of daily living score. |
| **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 or neuromuscular specialist. |
| **Coverage Duration** | Initial: 6 months. Recertifications: 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Covered for patients with a diagnosis of CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) confirmed by electrodiagnostic testing (consistent with EFNS/PNS guidelines) or other diagnostic test such as MRI or nerve biopsy. Must have documentation of an inadequate response, significant intolerance, or contraindication to BOTH of the following within previous 12 months: i. Corticosteroid treatment AND ii. Intravenous or subcutaneous immune globulin (IVIG or SCIG) treatment. Recertification requires documentation of significant clinical improvement in neurologic symptoms or stabilization of disease (measurement of response may include nerve conduction studies, objective clinical measurement tools (e.g. INCAT, Medical Research Council [MRC] sum score, grip strength, etc.) or physical exam showing improvement in neurological strength and sensation. Covered for the treatment of GENERALIZED MYASTHENIA GRAVIS (gMG) in patients who have a Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV and documentation of a baseline Myasthenia Gravis Activities of Daily Living (MG ADL) score of at least 5. Must also meet ONE of the following (A or B): A) corticosteroids for at least 3 months of treatment OR non-steroidal immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclosporine) for at least 3 months of treatment OR B) ONE immunosuppressive therapy (i.e., corticosteroid, non-steroidal immunosuppressive therapy [i.e., azathioprine, mycophenolate mofetil, cyclosporine]) AND at least one treatment of plasma exchange/plasmapheresis or intravenous immunoglobulin (IVIG). Recertification requires documentation of a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite) OR subjective/objective evidence from provider that use of drug 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** | |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# welireg

**Products Affected**

- WELIREG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis. For von Hippel-Lindau (VHL) disease only, 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). Covered for treatment of patients with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# xdemvy

**Products Affected**

- XDEMVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Microscopic examination of eyelashes showing Demodex mites. |
| **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** | Two months. |
| **Other Criteria** | Must have a diagnosis of Demodex blepharitis confirmed by microscopic examination of the eyelashes to detect Demodex mites. Must have bothersome symptoms of Demodex blepharitis (such as itchy eyelids, excessive eye tearing, light sensitivity, gritty or burning eye sensation). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 ANKYLOSING SPONDYLITIS (AS) in pts who have had serious side effects or drug failure w/ ONE of: Hadlima or Simlandi. TNF-blocker-experienced pts must have had serious side effects or drug failure with any AS-indicated TNF-blocker. Covered for 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: Hadlima or Simlandi. Covered for PSORIATIC ARTHRITIS (PsA) in patients aged 2 and up. Adult patients also must have had serious side effects or drug failure with ONE of: Hadlima or Simlandi. 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 ONE of: Hadlima or Simlandi. TNF-blocker-experienced patients must have had serious side effects or drug failure with any RA-indicated TNF-blocker. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in patients who have had inadequate response or intolerance with at least ONE 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
| --- | --- |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# xgeva

**Products Affected**

- BILPREVDA
- XGEVA
- XTRENBO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# xhance

**Products Affected**

- XHANCE

| 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 allergist, immunologist, otolaryngologist, or pulmonologist |
| **Coverage Duration** | One year. |
| **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 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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, pertinent lab/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 allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist. |
| **Coverage Duration** | Initial approval - 6 months. Recertifications - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For all shared indications, approval of Xolair requires intolerance, therapeutic failure or contraindication to Dupixent. Covered for the treatment of MODERATE TO SEVERE PERSISTENT ASTHMA. For ages 12 and older, pt. must be experiencing asthma exacerbations, and 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. 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. Upon recertification, documentation should be provided validating reduction in asthma exacerbations. Covered for the diagnosis of CHRONIC SPONTANEOUS URTICARIA in patients that have experienced at least a six-week history of urticaria, characterized by the development of pruritic wheals (hives), angioedema, or both. In addition, the patient must have a documented history of symptomatic failure of H1 antihistamine treatment and intolerance, therapeutic failure or contraindication to Dupixent. Upon recertification, documentation should be provided validating response to therapy (such as decreased severity of itching, decreased size of hives, decreased number of hives). Covered for a diagnosis of CHRONIC RHINOSINUSITIS WITH NASAL POLYPS with documentation of inadequate response to an 8 week trial of Xhance nasal spray and intolerance, therapeutic failure or contraindication to Dupixent. 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 symptoms, improved sense of smell). Covered for the treatment of IgE-MEDIATED FOOD ALLERGY in patients with single or multiple IgE-mediated food allergies. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# yonsa

**Products Affected**

- YONSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | As limited by FDA labeling. |
| **Required Medical Information** | Diagnosis as confirmed by elevated prostate-specific antigen (PSA) test and any one of the following: biopsy, imaging study or lab diagnostic test such as 4Kscore Test or Prostate Health Index (PHI). 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | 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 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), or 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

**INDEX OF DRUGS**


*abiraterone oral tablet 250 mg* ..... 97
ACTHAR ..... 2
ACTHAR SELFJECT ..... 2
ACTIMMUNE ..... 3
*adapalene topical cream* ..... 147
*adapalene topical gel 0.3 %* ..... 147
ADEMPAS ..... 111
AIMOVIG AUTOINJECTOR ..... 31
AKEEGA ..... 97
ALECENSA ..... 97
ALTRENO ..... 147
ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG ..... 97
ALUNBRIG ORAL TABLETS,DOSE PACK ..... 97
*ambrisentan oral tablet 10 mg, 5 mg* ..... 111
*amphetamine sulfate* ..... 10
*apomorphine* ..... 11
ARAZLO ..... 147
ARCALYST ..... 12
ARIKAYCE ..... 13
*armodafinil* ..... 131
*asenapine maleate* ..... 16
ATTRUBY ..... 14
AUGTYRO ORAL CAPSULE 160 MG, 40 MG ..... 97
AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG ..... 15
AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG ..... 15
AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG ..... 15
AUVELITY ORAL TABLET, IR AND ER, BIPHASIC ..... 16
AUVELITY ORAL TABLET,IR ER BIPHASIC,DOSEPACK ..... 16
AVMAPKI-FAKZYNJA ..... 97
AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG ..... 97
BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG 97
BENLYSTA SUBCUTANEOUS ..... 18
BESREMI ..... 19
BESREMI PEN ..... 19
*bexarotene topical* ..... 20
BILPREVDA ..... 171
*bosentan oral tablet 125 mg, 62.5 mg* ..... 111
BOSULIF ORAL CAPSULE 100 MG, 50 MG ..... 97
BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG ..... 97
*bosutinib oral tablet 100 mg, 400 mg, 500 mg* ..... 97
BOTOX ..... 21
BRAFTOVI ..... 22
BRINSUPRI ..... 23
BRUKINSA ORAL CAPSULE ..... 24
BRUKINSA ORAL TABLET ..... 24
*budesonide rectal* ..... 25
BYLVAY ..... 26
BYSANTI ..... 16
BYSANTI TITRATION PACK A ..... 16
BYSANTI TITRATION PACK B ..... 16
BYSANTI TITRATION PACK C ..... 16
CABLIVI INJECTION KIT ..... 27
CABOMETYX ..... 97
*calcipotriene-betamethasone* ..... 146
CALQUENCE ..... 24
CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG ..... 16
CAPRELSA ORAL TABLET 100 MG, 300 MG ..... 97
*carglumic acid* ..... 28
CAVHANZA ..... 97
CERDELGA ..... 30
CHOLBAM ..... 32
*chorionic gonadotropin, human intramuscular* ..... 33
*clomiphene citrate* ..... 34
COBENFY ORAL CAPSULE 100-20 MG, 125-30 MG, 50-20 MG ..... 16
COBENFY STARTER PACK ..... 16
COMETRIQ ..... 97
COPIKTRA ..... 97
CORTROPHIN GEL ..... 2
COSENTYX (2 SYRINGES) ..... 35
COSENTYX PEN (2 PENS) ..... 35
COSENTYX SUBCUTANEOUS SYRINGE 75 MG/0.5 ML ..... 35
COSENTYX UNOREADY PEN ..... 35
COTELLIC ..... 22
CUVRIOR ..... 37
*dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg* ..... 97
DAURISMO ORAL TABLET 100 MG, 25 MG ..... 97
*deflazacort oral suspension* ..... 38
*deflazacort oral tablet 18 mg, 30 mg, 36 mg, 6 mg* ..... 38
*dextromethorphan-quinidine* ..... 90
*dichlorphenamide* ..... 39
*diclofenac sodium topical gel 3 %* ..... 4
*dihydroergotamine nasal* ..... 40
DOJOLVI ..... 41
DOPTELET (10 TAB PACK) ..... 42
DOPTELET (15 TAB PACK) ..... 42
DOPTELET (30 TAB PACK) ..... 42
*doxepin topical* ..... 43
*dronabinol oral capsule* ..... 44
*droxidopa* ..... 45
DUOBRII ..... 146

DUPIXENT SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML ..... 46
DUPIXENT SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML ..... 46
ELREXFIO ..... 68
*eltrombopag olamine oral powder in packet 12.5 mg, 25 mg* ..... 109
*eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg* ..... 109
ENBREL MINI ..... 48
ENBREL SUBCUTANEOUS SOLUTION ..... 48
ENBREL SUBCUTANEOUS SYRINGE ..... 48
ENBREL SURECLICK ..... 48
ENSACOVE ..... 97
ENSPRYNG ..... 50
ENSTILAR ..... 146
EPIDIOLEX ..... 51
ERIVEDGE ..... 97
ERLEADA ORAL TABLET 240 MG, 60 MG ..... 52
EVENITY ..... 54
*everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg* ..... 97
*everolimus oral tablet for suspension 2 mg, 3 mg, 5 mg* ..... 97
EVRYSDI ORAL RECON SOLN ..... 56
EVRYSDI ORAL TABLET ..... 56
EXXUA ORAL TABLET EXTENDED RELEASE 24 HR ..... 16
EXXUA ORAL TABLET, EXT REL 24HR DOSE PACK ..... 16
FABIOR ..... 147
FANAPT ..... 16
FANAPT TITRATION PACK A ..... 16
FANAPT TITRATION PACK B ..... 16
FANAPT TITRATION PACK C ..... 16
FINTEPLA ..... 57
FIRDAPSE ..... 58
FOTIVDA ..... 97
FRUZAQLA ORAL CAPSULE 1 MG, 5 MG ..... 97
*gabapentin oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg* ..... 59
GAMMAGARD LIQUID ..... 71
GAMMAGARD LIQUID ERC ..... 71
GAMMAKED ..... 71
GAMUNEX-C ..... 71
GATTEX 30-VIAL ..... 60
GAVRETO ..... 97
*gefitinib* ..... 97
GILOTRIF ..... 97
*glutamine (sickle cell)* ..... 49
GOCOVRI ORAL CAPSULE,EXTENDED RELEASE 24HR 137 MG, 68.5 MG ..... 106
GOMEKLI ..... 97
HADLIMA ..... 6
HADLIMA (CITRATE-FREE) ..... 6
HADLIMA (CITRATE-FREE) PUSHTOUCH ..... 6
HADLIMA PUSHTOUCH ..... 6
HAEGARDA ..... 110
HARLIKU ..... 89
HERNEXEOS ..... 97
HIZENTRA ..... 126
HYQVIA ..... 126
HYRNUO ..... 97
IBRANCE ..... 29
IBTROZI ..... 97
*icatibant* ..... 5
ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG ..... 97
IDHIFA ..... 97
*imatinib oral tablet 100 mg, 400 mg* ..... 97
IMBRUVICA ORAL CAPSULE 140 MG, 70 MG ..... 24
IMBRUVICA ORAL SUSPENSION ..... 24
IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG ..... 24
IMKELDI ..... 97
IMPAVIDO ..... 65
INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE ..... 106
INCRELEX ..... 66
INGREZZA INITIATION PACK ..... 67
INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG ..... 67
INGREZZA SPRINKLE ORAL CAPSULE, SPRINKLE 40 MG, 60 MG, 80 MG ..... 67
INLURIYO ..... 97
INLYTA ORAL TABLET 1 MG, 5 MG ..... 97
INQOVI ..... 97
INREBIC ..... 97
ISTURISA ..... 69
ITOVEBI ORAL TABLET 3 MG, 9 MG ..... 97
IWILFIN ..... 97
JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG ..... 97
JAYPIRCA ORAL TABLET 100 MG, 50 MG ..... 24
JIDEYTRO ORAL TABLET 100 MG, 25 MG ..... 97
JOURNAVX ..... 72
JUXTAPID ORAL CAPSULE 10 MG, 2 MG, 20 MG, 30 MG, 5 MG ..... 73
KALYDECO ..... 74
KERENDIA ..... 75
KINERET ..... 76
KISQALI ..... 29
KISQALI FEMARA CO-PACK ORAL TABLET 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG ..... 29
KOMZIFTI ..... 97
KOSELUGO ..... 97
KRAZATI ..... 97

*lapatinib* ..... 97
LAZCLUZE ORAL TABLET 240 MG, 80 MG ..... 97
*lenalidomide* ..... 97
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) ..... 97
*leuprolide subcutaneous kit* ..... 62
*lidocaine topical adhesive patch,medicated 5 %* ..... 77
LIFYORLI ..... 97
LIVMARLI ORAL SOLUTION ..... 78
LIVMARLI ORAL TABLET 10 MG, 15 MG, 20 MG, 30 MG ..... 78
LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG ..... 97
LORBRENA ORAL TABLET 100 MG, 25 MG ..... 97
LUMAKRAS ..... 97
LUPKYNIS ..... 79
LYBALVI ORAL TABLET 10-10 MG, 15-10 MG, 20-10 MG, 5-10 MG ..... 80
LYNPARZA ..... 97
LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5) ..... 97
*macitentan* ..... 111
MAVYRET ORAL PELLETS IN PACKET ..... 81
MAVYRET ORAL TABLET ..... 81
MEKINIST ..... 22
MEKTOVI ..... 22
*memantine-donepezil* ..... 82
*methamphetamine* ..... 10
*mifepristone oral tablet 300 mg* ..... 83
*miglustat* ..... 84
MILOPHENE ..... 34
*modafinil oral tablet 100 mg, 200 mg* ..... 131
MODEYSO ..... 97
MOTPOLY XR ORAL CAPSULE,EXTENDED RELEASE 24HR 100 MG, 150 MG, 200 MG ..... 86
MYALEPT ..... 87
MYTESI ..... 88
NERLYNX ..... 97
*nilotinib hcl* ..... 97
NINLARO ..... 97
*nintedanib* ..... 92
*nitisinone* ..... 89
NITYR ..... 89
NOURIANZ ..... 106
NUBEQA ..... 97
NUEDEXTA ..... 90
NUPLAZID ..... 91
NURTEC ODT ..... 85
OCTAGAM ..... 71
ODOMZO ..... 97
OFEV ..... 92
OGSIVEO ORAL TABLET 100 MG, 150 MG ..... 97
OJEMDA ..... 97
OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG ..... 97
OMNITROPE ..... 63
ONUREG ..... 97
OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG ..... 16
OPSUMIT ..... 111
OPSYNVI ..... 111
OPZELURA ..... 95
ORENCIA (WITH MALTOSE) ..... 99
ORENCIA CLICKJECT ..... 99
ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML ..... 99
ORENITRAM ..... 111
ORENITRAM MONTH 1 TITRATION KT ..... 111
ORENITRAM MONTH 2 TITRATION KT ..... 111
ORENITRAM MONTH 3 TITRATION KT ..... 111
ORGOVYX ..... 100
ORIAHNN ..... 101
ORILISSA ORAL TABLET 150 MG, 200 MG ..... 102
ORKAMBI ORAL GRANULES IN PACKET ..... 103
ORKAMBI ORAL TABLET ..... 103
ORMALVI ..... 39
ORSERDU ORAL TABLET 345 MG, 86 MG ..... 97
OTEZLA ..... 104
OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20 MG (51), 10 MG (4)-20 MG (4)-30 MG (47) ..... 104
OTEZLA XR ..... 104
OTEZLA XR INITIATION ..... 104
OXERVATE ..... 105
OZEMPIC ..... 61
*pazopanib oral tablet 200 mg, 400 mg* ..... 97
PEMAZYRE ..... 97
PHESGO ..... 68
PIQRAY ..... 97
*pirfenidone oral capsule* ..... 107
*pomalidomide* ..... 97
POMALYST ..... 97
PREGNYL ..... 33
PRIVIGEN ..... 71
PROCRIT ..... 53
PROCYSBI ..... 108
PROLASTIN-C INTRAVENOUS SOLUTION ..... 8
PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG ..... 109
PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG ..... 109
PYRUKYND ORAL TABLET 20 MG, 5 MG, 5 MG (4-WEEK PACK), 50 MG ..... 113
PYRUKYND ORAL TABLETS,DOSE PACK ..... 113

QINLOCK ..... 97
*quinine sulfate* ..... 114
RADICAVA ORS STARTER KIT SUSPENSION ..... 115
RECORLEV ..... 116
RELISTOR ORAL ..... 94
RELISTOR SUBCUTANEOUS SOLUTION ..... 94
RELISTOR SUBCUTANEOUS SYRINGE 12 MG/0.6 ML, 8 MG/0.4 ML ..... 94
RETACRIT ..... 53
RETEVMO ORAL TABLET ..... 97
REVCOVI ..... 117
REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG ..... 97
REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG ..... 16
REZDIFFRA ORAL TABLET 100 MG, 60 MG, 80 MG ..... 119
REZLIDHIA ..... 97
REZUROCK ..... 121
RINVOQ LQ ..... 122
RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG ..... 122
ROMVIMZA ..... 97
ROZLYTREK ORAL CAPSULE 100 MG, 200 MG ..... 97
ROZLYTREK ORAL PELLETS IN PACKET ..... 97
RUBRACA ..... 97
RYBELSUS ..... 61
RYDAPT ..... 97
*sapropterin* ..... 125
SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG ..... 97
SECUADO ..... 16
SELARSDI SUBCUTANEOUS SOLUTION ..... 153
SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML ..... 153
SIGNIFOR ..... 127
*sildenafil (pulmonary hypertension) oral tablet* ..... 111
SIMLANDI (CITRATE-FREE) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML ..... 6
SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML, 80 MG/0.8 ML ..... 6
SIVEXTRO ..... 128
SKYCLARYS ..... 129
SKYRIZI SUBCUTANEOUS PEN INJECTOR ..... 130
SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 55 MG/0.37 ML ..... 130
SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML) ..... 130
*sodium oxybate* ..... 132
SOMAVERT ..... 1
*sorafenib* ..... 97
SPIRIVA RESPIMAT ..... 133
STELARA SUBCUTANEOUS SOLUTION ..... 153
STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML ..... 153
STIVARGA ..... 97
*sunitinib malate* ..... 97
SUNOSI ORAL TABLET 150 MG, 75 MG ..... 131
SYMDEKO ORAL TABLETS, SEQUENTIAL 100-150 MG (D)/ 150 MG (N), 50-75 MG (D)/ 75 MG (N) ..... 134
SYNDROS ..... 135
TABRECTA ..... 97
*tadalafil (pulmonary hypertension)* ..... 111
*tadalafil oral tablet 2.5 mg, 5 mg* ..... 136
TAFINLAR ..... 22
TAGRISSO ..... 97
TAKHZYRO SUBCUTANEOUS SOLUTION ..... 110
TAKHZYRO SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML (150 MG/ML) ..... 110
TALZENNA ..... 97
TARPEYO ..... 138
TASIGNA ..... 97
*tasimelteon* ..... 139
*tavaborole* ..... 93
TAVNEOS ..... 140
*tazarotene* ..... 147
TAZVERIK ..... 97
TEPMETKO ..... 97
*teriparatide* ..... 141
*tetrabenazine oral tablet 12.5 mg, 25 mg* ..... 169
THALOMID ORAL CAPSULE 100 MG, 50 MG 143
TIBSOVO ..... 97
*tolvaptan (polycys kidney dis) oral tablet 15 mg, 30 mg* ..... 145
*tolvaptan (polycys kidney dis) oral tablets, sequential 15 mg (am)/ 15 mg (pm), 30 mg (am)/ 15 mg (pm), 45 mg (am)/ 15 mg (pm), 60 mg (am)/ 30 mg (pm), 90 mg (am)/ 30 mg (pm)* 145
*tolvaptan oral tablet 15 mg, 30 mg* ..... 124
TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION ..... 62
*tretinoin* ..... 147
TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL ..... 148
TRIKAFTA ORAL TABLETS, SEQUENTIAL ..... 148
TRILITAS ..... 147
TRIPTODUR ..... 149
TRULICITY ..... 61
TRUQAP ..... 97
TUKYSA ORAL TABLET 150 MG, 50 MG ..... 97
TURALIO ..... 97
TYENNE AUTOINJECTOR ..... 144

TYENNE SUBCUTANEOUS ..... 144
TYVASO ..... 150
TYVASO INSTITUTIONAL START KIT ..... 150
TYVASO REFILL KIT ..... 150
TYVASO STARTER KIT ..... 150
UPTRAVI ORAL TABLET 1,000 MCG, 1,200 MCG, 1,400 MCG, 1,600 MCG, 100 MCG, 150 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG ..... 111
UPTRAVI ORAL TABLETS,DOSE PACK ..... 111
*ursodiol oral capsule 200 mg, 400 mg* ..... 152
*ustekinumab subcutaneous solution* ..... 153
*ustekinumab subcutaneous syringe 45 mg/0.5 ml, 90 mg/ml* ..... 153
VALCHLOR ..... 155
VANFLYTA ..... 97
VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG ..... 97
VENCLEXTA STARTING PACK ..... 97
VEPPANU ORAL TABLET 100 MG, 200 MG ..... 156
VERKAZIA ..... 157
VERQUVO ORAL TABLET 10 MG, 2.5 MG, 5 MG ..... 158
VERZENIO ..... 29
VIJOICE ORAL GRANULES IN PACKET ..... 159
VIJOICE ORAL TABLET 125 MG, 250 MG/DAY (200 MG X1-50 MG X1), 50 MG ..... 159
VITRAKVI ORAL CAPSULE 100 MG, 25 MG ..... 97
VITRAKVI ORAL SOLUTION ..... 97
VIVJOA ..... 160
VIZIMPRO ..... 97
VONJO ..... 97
VORANIGO ORAL TABLET 10 MG, 40 MG ..... 97
*voriconazole intravenous recon soln* ..... 161
*voriconazole-hpbcd* ..... 161
VOWST ..... 162
VRAYLAR ..... 16
VYNDAMAX ..... 137
VYNDAQEL ..... 137
VYVGART HYTRULO SUBCUTANEOUS SYRINGE ..... 163
WELIREG ..... 165
WINREVAIR ..... 111
XALKORI ..... 97
XDEMVY ..... 166
XELJANZ ORAL SOLUTION ..... 167
XELJANZ ORAL TABLET ..... 167
XELJANZ XR ..... 167
XERMELO ..... 170
XGEVA ..... 171
XHANCE ..... 172
XOLAIR ..... 173
XOSPATA ..... 97
XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (10 MG X 4), 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), 80 MG/WEEK (80 MG X 1), 80MG TWICE WEEK (160 MG/WEEK) ..... 97
XTANDI ORAL CAPSULE ..... 97
XTANDI ORAL TABLET 40 MG, 80 MG ..... 97
XTRENBO ..... 171
YESINTEK SUBCUTANEOUS SOLUTION ..... 153
YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML ..... 153
YONSA ..... 175
YUTREPIA ..... 111
ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG ..... 97
ZELBORAF ..... 22
ZOLINZA ..... 97
ZTALMY ..... 176
ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG ..... 177
ZYDELIG ..... 97
ZYKADIA ..... 97