# AAT DEFICIENCY

## Products Affected

- ARALAST NP
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of severe congenital A1-PI deficiency who have clinically evident emphysema, weight, A1-PI phenotype, A1-PI baseline level |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a pulmonologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ABILIFY IM

## Products Affected

- ABILIFY MAINTENA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis and other treatments tried and outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a psychiatrist or mental health specialist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must a have a reason aripiprazole oral cannot be used. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTIMMUNE

## Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by a hematologist, oncologist, immunologist, infectious diseases specialist, or endocrinologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ACTINIC KERATOSIS

## Products Affected

- *diclofenac sodium topical gel 3 %*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Prior use of 5% fluorouracil topical and 5% imiquimod topical, unless contraindicated. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADAPALENE

## Products Affected

- *adapalene topical cream*
- *adapalene topical gel 0.3 %*
- *adapalene topical gel with pump*
- *adapalene topical solution*
- *adapalene topical swab*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved when used to treat photo aging. |
| **Required Medical Information** | Diagnosis, previous treatments, and response therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Must have failure, intolerance, or contraindication to tretinoin |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADBRY

## Products Affected

- ADBRY SUBCUTANEOUS AUTO-INJECTOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, evidence of prior therapy with a topical steroid and topical immunomodulator. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information |
| **Prescriber Restrictions** | Prescribing limited to an allergist, immunologist, pulmonologist, otolaryngologist or dermatologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For atopic dermatitis: trial of least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ADEMPAS

## Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Confirmation of diagnosis, documentation of response to any prior therapies |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by pulmonologist or cardiologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For WHO Group 1 diagnosis, patient must have a history of taking or contraindication to sildenafil (Revatio). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AFINITOR

## Products Affected

- *everolimus (antineoplastic) oral tablet*
- *everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST OR NEUROLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AIMOVIG

## Products Affected

- AIMOVIG AUTOINJECTOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried, and outcome. Member has been evaluated for and does not have medication overuse headache. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AJOVY

## Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried, and outcome. Member has been evaluated for and does not have medication overuse headache. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 years |
| **Other Criteria** | Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AKEEGA

## Products Affected

- AKEEGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Member must have metastasis from malignant tumor of prostate, Castration-resistant, deleterious or suspected deleterious BRCA-mutated. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by an Oncologist or Urologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ALK POSITIVE TYROSINE KINASE INHIBITORS

## Products Affected

- ALECENSA
- XALKORI ORAL CAPSULE
- XALKORI ORAL PELLET 150 MG, 20 MG, 50 MG
- ZYKADIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ALUNBRIG

## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Metastatic non-small cell lung cancer (NSCLC): must be ALK-positive, as detected by an approved test. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AMIFAMPRIDINE

## Products Affected

- FIRDAPSE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Must have a documented diagnosis of Lamber-Eaton with electrodiagnostic studies including repetitive nerve stimulation and anti-P/Q-type voltage-gated calcium channel (VGCC) antibody testing to confirm the diagnosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ANALEPTIC

## Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Excessive sleepiness due to SWSD defined as the patient is working at least 5 overnight shifts per month. As adjunctive/augmentation treatment for depression in the adult if the patient is concurrently receiving other medication therapy for depression. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ANTIDEPRESSANTS

## Products Affected

- AUVELITY
- FETZIMA ORAL CAPSULE,EXT REL 24HR DOSE PACK 20 MG (2)- 40 MG (26)
- FETZIMA ORAL CAPSULE,EXTENDED RELEASE 24 HR
- TRINTELLIX
- *vilazodone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS, PRIOR THERAPIES TRIED AND FAILED |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For treatment of major depressive disorder (MDD), must have tried two generic antidepressants from different classes: SSRIs, SNRIs, TCAs, NOREPINEPHRINE-DOPAMINE REUPTAKE INHIBITORS, or NORADRENERGIC and SPECIFIC SEROTONERGIC ANTIDEPRESSANTS. Examples include: sertraline, citalopram, escitalopram, fluoxetine, paroxetine, venlafaxine, duloxetine, bupropion, amitriptyline, doxepin, etc. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ANTIPSYCHOTICS

## Products Affected

- *asenapine maleate*
- CAPLYTA
- FANAPT ORAL TABLET
- FANAPT ORAL TABLETS,DOSE PACK
- REXULTI ORAL TABLET
- SECUADO
- VERSACLOZ
- VRAYLAR ORAL CAPSULE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and treatement history. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For BIPOLAR DISORDER or SCHIZOPHRENIA, documentation of diagnosis, and treatment failure with two atypical anti-psychotics: ZIPRASIDONE, RISPERIDONE, QUETIAPINE, OLANZAPINE, CLOZAPINE, ARIPIPRAZOLE) or rationale as to why alternatives are not suitable. For treatment of major depressive disorder (MDD), must have tried generic antidepressants from at least two different classes: SSRIs, SNRIs, TCAs, NOREPINEPHRINE-DOPAMINE REUPTAKE INHIBITORS, or NORADRENERGIC and SPECIFIC SEROTONERGIC ANTIDEPRESSANTS. For Diagnosis of agitation due to dementia-Alzheimer's disease: documentation of diagnosis. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# APREPITANT

## Products Affected

- *aprepitant*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For use with highly and moderately-emetogenic chemotherapy, provide the chemotherapy regimen including drug, dose, and frequency. Ondansetron is preferred for post-operative nausea/vomiting (PONV) prophylaxis. When aprepitant is used for PONV prophylaxis, provide rationale as to why ondansetron is not a suitable alternative. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Request will also be reviewed for coverage under part B versus part D. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ARCALYST

## Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 YEAR AT A TIME |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ARIKAYCE

## Products Affected

- ARIKAYCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including sputum culture supporting the diagnosis of Mycobacterium avium complex (MAC) lung disease must be submitted. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | For initial review, documentation of failure to obtain negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. For reauthorization, documentation of a negative sputum culture obtained within the last 30 days must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ATTRUBY

## Products Affected

- ATTRUBY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Confirmation of diagnosis with appropriate testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a cardiologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AUGTYRO

## Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# AYVAKIT

## Products Affected

- AYVAKIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or gastroenterologist - or - an allergist or immunologist, as appropriate to the diagnosis. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For GIST: documentation of a PDGFRA exon 18 mutation or PDGFRA D842V mutation. For AdvSM, documentation of platelet count greater than 50 X 10-9th/L. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BALVERSA

## Products Affected

- BALVERSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BANZEL

## Products Affected

- *rufinamide*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by a specialist appropriate to the disease state such as a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For Lennox-Gastaut Syndrome:  documenation of treatment with valproate and lamotrigine with outcomes (treatment failure or intolerance). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BENLYSTA

## Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Severe active lupus nephritis, active central nervous, use in combination with other biologics |
| **Required Medical Information** | Diagnosis, autoantibody testing, prior treatments including response |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a rheumatologist or nephrologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Failed to demonstrate adequate response to TWO standard therapies at recommended doses: corticosteroids, antimalarials, NSAIDs, and/or immunosuppressants. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BESREMI

## Products Affected

- BESREMI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior treatments, and outcome |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Must have an intolerance, contraindication, or treatment failure with hydroxyurea and Peginterferon alpha-2a. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BOSULIF

## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to bosutinib. CBC and LFT lab test results are needed for continuation treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Trial of OR intolerance/contraindication to imatinib. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BRAFTOVI

## Products Affected

- BRAFTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BRIVIACT

## Products Affected

- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used and result of prior therapy. If continuation, response to brivaracetam. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by neurologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Failure of treatment with levetiracetam and ONE additional Part D formulary anticonvulsant drug. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BRONCHITOL

## Products Affected

- BRONCHITOL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has a diagnosis of cystic fibrosis (CF) |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by pulmonologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# BRUKINSA

## Products Affected

- BRUKINSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CABOMETYX

## Products Affected

- CABOMETYX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CALQUENCE

## Products Affected

- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | NA |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by oncology |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CAPRELSA

## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | HISTORY OF CONGENITAL LONG QT SYNDROME |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | ECG, ELECTROLYTE(K,Mg,Ca), AND TSH MONITORING AT BASELINE, 2-4 WEEKS AND 8-12 WEEKS AFTER STARTING TREATMENT AND EVERY 3 MONTHS THEREAFTER |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CINQAIR

## Products Affected

- CINQAIR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Administration of reslizumab requires a specialized care setting and requires an experienced clinician prepared to manage anaphylaxis will not be approved for self-administration |
| **Required Medical Information** | Allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Pulmonology or Immunologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patient must be diagnosed with severe asthma, currently receiving inhaled and/or oral corticosteroid treatment, have a baseline eosinophil count of 400/mcL, have a contraindication, intolerance or failure of Nucala. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COBENFY

## Products Affected

- COBENFY
- COBENFY STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and treatement history. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For SCHIZOPHRENIA, documentation of diagnosis, and treatment failure with two atypical anti-psychotics: (ZIPRASIDONE, RISPERIDONE, QUETIAPINE, OLANZAPINE, CLOZAPINE, ARIPIPRAZOLE) or rationale as to why alternatives are not suitable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COMETRIQ

## Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COPIKTRA

## Products Affected

- COPIKTRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CORLANOR

## Products Affected

- CORLANOR ORAL SOLUTION
- *ivabradine*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For heart failure in adult patients, only: ejection fraction less than or equal to 35% AND heart rate greater than 70 beats per minute AND in sinus rhythm AND on maximally tolerated beta-blocker OR has contraindication to beta-blocker (i.e.. allergy, severe COPD limiting beta blocker usage). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a cardiologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COSENTYX

## Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- COSENTYX SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML
- COSENTYX UNOREADY PEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other treatments tried and reasons for failure. Regular monitoring for TB required, both at baseline and during treatment |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribing limited to a rheumatologist or dermatologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine and methotrexate. For hidradenitis suppurativa: patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. Note: every two-week dosing requires demonstration of treatment failure of every four-week dosing. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# COTELLIC

## Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CYCLOBENZAPRINE

## Products Affected

- *cyclobenzaprine oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Medical records documenting diagnosis and prior use of or contraindication to tizanidine. |
| **Age Restrictions** | Patients aged less than 65 years are approved. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patient must have an inadequate response, contraindication, or intolerance to tizanidine. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# CYSTADROP

## Products Affected

- CYSTADROPS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Presribing limited to opthalmologist or corneal specialist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | To start treatment, documentation of presence of corneal cystine crystal accumulation by slit lamp examination, baseline Corneal Cystine Cystal Score (CCCS) provided. For continuation: positive response to therapy (e.g., documentation showing improvement in vision with less pain and photophobia). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DAURISMO

## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DAYBUE

## Products Affected

- DAYBUE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Rett disorder. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DEMSER

## Products Affected

- *metyrosine*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and whether the patient is a candidate for surgery |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DIABETIC SUPPLIES

## Products Affected

- *alcohol pads*
- GAUZE PADS 2 X 2
- INSULIN PEN NEEDLE
- INSULIN SYRINGE (DISP) U-100 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE
- NEEDLES, INSULIN DISP.,SAFETY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DIACOMIT

## Products Affected

- DIACOMIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | There is no clinical data to support the use of Diacomit alone to treat Dravet syndrome. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documentation must show co-administration of stiripentol with clobazam. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DIFICID

## Products Affected

- DIFICID ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior treatments, response to treatment |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | 1 month |
| **Other Criteria** | History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DOPTELET

## Products Affected

- DOPTELET (10 TAB PACK)
- DOPTELET (15 TAB PACK)
- DOPTELET (30 TAB PACK)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and platelet count. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a specialist appropriate to the disease state such as a hematologist, oncologist, or gastroenterologist. |
| **Coverage Duration** | 1 month for chronic liver disease, 6 months for chronic immune thrombocytopenia. |
| **Other Criteria** | For chronic liver disease-associated thrombocytpenia, the patient must be scheduled to undergo a pre-planned medical or dental procedure with treatment beginning 10 to 13 days prior to the scheduled procedure. Patients should undergo the procedure 5 to 8 days after the last dose. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DRIZALMA

## Products Affected

- DRIZALMA SPRINKLE ORAL
  CAPSULE, DELAYED REL SPRINKLE
  20 MG, 30 MG, 40 MG, 60 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Need reason why Duloxetine oral capsule cannot be used. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DRONABINOL

## Products Affected

- *dronabinol*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not covered for the treatment of pain. |
| **Required Medical Information** | Diagnosis, previous treatments, and the outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For cancer related weight loss, must have a treatment failure or intolerance to megestrol. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DUPIXENT

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribing limited to an allergist, immunologist, pulmonologist, otolaryngologist, dermatologist or gastroenterologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For atopic dermatitis: a trial on at least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus). Immunomodulators will not be required for patients under 2 years of age. For chronic rhinosinusitis with nasal polyps (CRS with NP): documentation of inflammatory persistence for 12 weeks or longer and a trial of of a intranasal corticosteroId product (beclomethasone, fluticasone, mometasone). For Asthma: baseline eosinophil count of 150 cells/mcL or greater within previous 12 months. Patient has received combination therapy with an inhaled corticosteroid and at least two of the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist or an interleukin drug (montelukast, zafirlukast). For Prurigo nodularis: Documentation of Diagnosis of prurigo nodularis. a trial on at least one topical corticosteroid (fluticasone, fluocinonide, desonide). For Eosinophilic Esophagitis: Documentation of eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of greater than or equal to 15 intraepithelial eosinophils per high power field (HPF) (or 60 eosinophils per mm2 ). Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least one |

| PA Criteria | Criteria Details |
|---|---|
| | of the following: Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone) |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# DUVYZAT

## Products Affected

- DUVYZAT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Medical records supporting the request including genetically confirmed diagnosis of Duchenne muscular dystrophy (DMD). Baseline function tests (e.g. time to wheelchair assistance, required respiratory assistance/pulmonary function tests, 4SC, 6MWT, time to walk/run 10 meters [10MWT], or NSAA) are documented. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by or in consultation with a specialist (e.g. neurologist) with experience in the treatment of DMD. |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Patient is ambulatory upon initiation of therapy. Patient is stable on baseline corticosteroids for 6 months. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with biologic therapy or targeted synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA/AS/JIA/JRA, prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist. PP, prescribed by or in consult w/ dermatologist.GVHD, prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center.Behcet's disease, prescribed by or in consult w/ rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) |

| PA Criteria | Criteria Details |
|---|---|
| | OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic coricosteroid, immunosuppressives, Humira or an infliximab product.RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENDARI

## Products Affected

- *glutamine (sickle cell)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has a diagnosis of sickle cell disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Patients must have an inadequate response, contraindication, or intolerance to hydroxyurea. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ENVARSUS XR

## Products Affected

- ENVARSUS XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including diagnosis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a transplant specialist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Must have failure, intolerance, or contraindication to immediate release tacrolimus. Will also be reviewed for BvD. |
| **Indications** | Some FDA-approved Indications Only. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, response to treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by or in consultation with a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For Lennox-Gastaut Syndrome: documentation of use of valproate and lamotrigine and outcomes (treatment failure or intolerance). For Dravet Syndrome: documentation of use of valproate and topiramate and outcomes (treatment failure or intolerance). For refractory seizures: documentation of use of two different anti-convulsant drugs from different pharmacologic classes (valproate, topiramate, lamotrigine or similar) and outcomes (intolerance or treatment failure). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# EPRONTIA

## Products Affected

- EPRONTIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and prior treatment with oral topiramate (either tablet or capsule) and response to treatment including if contraindicated. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 Years |
| **Other Criteria** | Must have a intolerance, contraindication, or medical reason the tablet or capsule are not acceptable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERGOTAMINE DERIVATIVES

## Products Affected

- *dihydroergotamine nasal*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior treatments and responses. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by a headache specialist, pain management specialist or neurologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For treatment of migraine, unless contraindicated, a trial and failure of two different triptans (covered on the formulary): one oral tablet and one other formulation, either nasal spray or injection. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERIVEDGE

## Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | PATIENTS WHO ARE CANDIDATES FOR SURGERY OR RADIATION |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY A ONCOLOGIST OR DERMATOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERLEADA

## Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and outcome, fall risk assessment, and seizure history (if any) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by an oncologist or urologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For metastatic castration resistant prostate cancer (CRPC) -- OR -- metastatic castration-sensitive prostate cancer (CSPC), patient must have a failure, intolerance, or contraindication to abiraterone (Zytiga) prior to initiation of therapy with apalutamide (Erleada). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ERYTHROPOIESIS STIMULATING AGENTS

## Products Affected

- ARANESP (IN POLYSORBATE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (IN POLYSORBATE) INJECTION SYRINGE
- EPOGEN INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment. |
| **Required Medical Information** | Pre-treatment hemoglobin level less than 10 g/dL AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies - prescribed by an oncologist/hematologist. Surgery - Prescribed by a surgeon. HIV - Prescribed by an infectious disease specialist. |
| **Coverage Duration** | Initial: 3 months. Renewal: CKD-12 months, Non-myeloid cancers, HIV-4 months. Surgery-3 months |
| **Other Criteria** | For renewal of CKD, for dialysis patients: Hb less than 11 g/dL or physician will decrease or interrupt dose and for non-dialysis patients: Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks. For renewal of zidovudine-treated HIV, Hb is 12g/dL or less AND Zidovudine dose remains 4,200 mg/week or less and there is a measurable response after eight weeks (defined as an increase in Hb or a reduction in RBC transfusion requirements or documented dose escalation [up to max of 300 units/kg/dose]) |

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

# FASENRA

## Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SYRINGE 10 MG/0.5 ML, 30 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by a Pulmonologist or Immunologist or Allergist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Patient must be diagnosed with severe asthma, currently receiving inhaled and/or oral corticosteroid treatment, AND have a baseline eosinophil count of 150 cells/mcL or greater within previous 12 months. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FILSUVEZ

## Products Affected

- FILSUVEZ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Epidermolysis Bullosa |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | n/a |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FINTEPLA

## Products Affected

- FINTEPLA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FORTEO

## Products Affected

- *teriparatide subcutaneous pen injector 20 mcg/dose (560mcg/2.24ml)*
- TERIPARATIDE SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (620MCG/2.48ML)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for a cumulative lifetime duration of abaloparatide and any other parathyroid hormone therapy (eg, teriparatide) of more than 2 years. Not approved for combination therapy of a PTH/PTHrP analog in combination with other osteoporosis agents. |
| **Required Medical Information** | Diagnosis, fracture history, prior therapy used and response to prior therapy. Required pretreatment testing: DXA, if not performed in the past two years: serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D), and, 24-hour urine calcium, creatinine (or fasting specimen for calcium/creatine ratio) to evaluate for baseline hypercalciuria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an endocrinologist. |
| **Coverage Duration** | 2 years |
| **Other Criteria** | Documentation of a trial on an oral bisphosphonate, or, if GI intolerant of oral bisphosphonates, use of a parenteral bisphosphonate - AND - a trial on denosumab. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# FOTIVDA

## Products Affected

- FOTIVDA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, response to tivozanib. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a specialist in hematology / oncology. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documentation of two prior lines of systemic drug therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FRUZAQLA

## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Colorectal cancer, Metastatic, previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy if RAS wild-type and medically appropriate |
| **Age Restrictions** | Member is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# FYCOMPA

## Products Affected

- FYCOMPA ORAL SUSPENSION
- FYCOMPA ORAL TABLET 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be prescribed by neurologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Monitor at initiation and after dose increases for serious psychiatric and/or behavioral reactions. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GATTEX

## Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Therapy should be discontinued in cases of intestinal malignancy. |
| **Required Medical Information** | Diagnosis, other therapies tried and treatment responses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a gastroenterologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For ADULT patients: A colonoscopy of the entire colon with removal of polyps must be done before initiating therapy, medical records documenting this procedure must be submitted. For PEDIATRIC patients: Perform fecal occult blood testing: if there is unexplained blood in the stool, perform colonoscopy / sigmoidoscopy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GAUCHER'S DISEASE TREATMENT

## Products Affected

- CERDELGA
- *miglustat*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | NOT APPROVED FOR TYPE II OR TYPE III GAUCHER'S DISEASE |
| **Required Medical Information** | Diagnosis. For MIGLUSTAT: rationale as to why ERT is not appropriate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY GENETICIST, HEMATOLOGIST, HEPATOLOGIST OR METABOLIC SPECIALIST |
| **Coverage Duration** | 3 years |
| **Other Criteria** | USE OF MIGLUSTAT IS RESERVED FOR THOSE WHOM ENZYME REPLACEMENT THERAPY IS NOT AN OPTION |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GAVRETO

## Products Affected

- GAVRETO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or pulmonologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Diagnosis of non-small cell lung cancer (NSCLC) or Thyroid cancer that is verified by an FDA-approved diagnostic test to have rearranged during transfection (RET) fusion mutations. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GILOTRIF

## Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GLEOSTINE

## Products Affected

- GLEOSTINE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GLP1

## Products Affected

- MOUNJARO
- TRULICITY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not covered for weight loss |
| **Required Medical Information** | Documented diagnosis of Type 2 diabetes. Submitted A1C from past 6 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Type 2 diabetes: Member has tried and failed metformin ER (at maximum tolerated dose for 3 months) or has an intolerance or contraindication, and one other anti-diabetic drug from a different class. Exceptions are permitted for beneficiaries with type 2 diabetes and multiple cardiovascular risk factors or established cardiovascular disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GRALISE

## Products Affected

- *gabapentin oral tablet extended release 24 hr*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and previous treatments, including dosage and outcome of previous treatments. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have a documented intolerance, contraindication to, or failure of generic regular relase gabapentin titrated to maximum tolerated dosage or rationale as to why generic regular release gabapentin cannot be used. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# GROWTH HORMONE

## Products Affected

- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | PRESENCE OF CONTRAINDICATIONS TO THERAPY |
| **Required Medical Information** | DIAGNOSIS, HEIGHT AND WEIGHT, HISTORY OF GROWTH MEASUREMENT. REPLACEMENT THERAPY IN PATIENTS WITH GROWTH HORMONE DEFICIENCY WITH DIAGNOSIS CONFIRMED BY APPROPRIATE GROWTH HORMONE STIMULATION TESTING |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an an endocrinologist or nephrologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Replacement therapy in patients with growth hormone deficiency with diagnosis confirmed by appropriate growth hormone stimulation testing. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HADLIMA

## Products Affected

- ADALIMUMAB-FKJP SUBCUTANEOUS PEN INJECTOR KIT
- ADALIMUMAB-FKJP SUBCUTANEOUS SYRINGE KIT
- HADLIMA
- HADLIMA PUSHTOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSHTOUCH

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another biologic DMARD or targeted synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | RA: patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). JIA/JRA: patient has tried another a non-biologic DMARD (e.g., MTX, sulfasalazine, leflunomide, NSAID) - or - biologic DMARD (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP: approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (e.g., MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional agent first) OR 2) patient has a |

| PA Criteria | Criteria Details |
|---|---|
| | contraindication to MTX as determined by the prescribing physician. CD: patient has tried corticosteroids (CSs), or if CSs are contraindicated, or if pt currently on CSs, or patient has tried one other agent for CD (e.g., azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR patient had ilecolonic resection or enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC: patient has tried a systemic therapy (e.g., 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS: patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. For all indications (excepting hidradenitis suppurativa), weekly dosing requires demonstration of treatment failure of every other week dosing. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HEMADY

## Products Affected

- HEMADY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of multiple myeloma. Medical records supporting the request. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Presribing limited to hematologist or oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HEPATITIS C TREATMENT

## Products Affected

- MAVYRET ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | PATIENT WEIGHT, GENOTYPE, HCV-RNA , LEVEL OF FIBROSIS, TREATMENT HISTORY |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY GASTROENTEROLOGIST, HEPATOLOGIST, OR INFECTIOUS DISEASE SPECIALIST |
| **Coverage Duration** | 8 - 24 WEEKS. TREATMENT WILL BE APPROVED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HEREDITARY ANGIOEDEMA

## Products Affected

- HAEGARDA
- *icatibant*
- ORLADEYO
- *sajazir*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Dual prescribing of injectable and oral formulations for HAE prophylaxis are not covered to prevent risk of double-dosing. |
| **Required Medical Information** | Diagnosis and the results of immunologic laboratory testing that show low C4 and functional C1- inhibitor levels (less than the lower limits of laboratory reference ranges). |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an allergist or immunologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For icatibant initiation: Member is 18 years of age and older, with confirmed diagnosis of HAE. To continue icatibant in patients who have treated previous acute HAE attacks with icatibant: documentation demonstrating a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity). To initiate berotralstat (Orladeyo: Member is aged 12 or older. Confirmed diagnosis of HAE. To initiate C1 esterase inhibitor, (Haegarda): Member is aged 6 or older. Confirmed diagnosis of HAE. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# HETLIOZ

## Products Affected

- *tasimelteon*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by a sleep specialist or neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For a diagnosis of non-24-hour sleep-wake disorder, submit sleep log through a wrist activity monitor that supports diagnosis of non-24-hour sleep-wake disorder) AND sleep study has ruled out sleep apnea and periodic limb movement disorder. For continuation, positive clinical response demonstrated by: (1) increased total nighttime sleep and, (2) decreased daytime nap duration, as determined by treating physician. For nighttime sleep disturbances in Smith-Magenis Syndrome, documentation supporting the diagnosis. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IBRANCE (S)

## Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and previous therapies tried. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must have a trial of either Kisqali or Verzenio prior to approval of Ibrance. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ICLUSIG

## Products Affected

- ICLUSIG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Liver function monitoring required at baseline and 3 months after initiation |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IDHIFA

## Products Affected

- IDHIFA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be prescribed by oncologist, hematologist, or transplant specialist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IMKELDI

## Products Affected

- IMKELDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | n/a |
| **Required Medical Information** | Diagnosis and prior treatment with oral imatinib tablet and response to treatment including if contraindicated |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by or in consultation with an oncologist, hematologist, allergist, or dermatologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have an intolerance, contraindication, or medical reason why imatinib tablet is not acceptable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IMPAVIDO

## Products Affected

- IMPAVIDO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including documentation of leishmaniasis diagnosis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | 1 month |
| **Other Criteria** | n/a |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INBRIJA

## Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to LEVODOPA ORAL INHALATION. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a neurologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Required trial and failure of: 1) both carbidopa/levodopa IR and ER and, 2) at least one other Parkinson's Disease drug: entacapone, pramipexole, ropinirole, selegiline, rasagiline, or amantadine. Intention to continue use of carbidopa/levodopa. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS, HEIGHT AND WEIGHT MEASUREMENTS, GH LEVEL, IGF-1 LEVEL |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ENDOCRINOLOGIST |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INHALED TOBRAMYCIN

## Products Affected

- TOBI PODHALER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by Infectious disease specialist or pulmonologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INLYTA

## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY A ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INQOVI

## Products Affected

- INQOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a hematologist / oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INREBIC

## Products Affected

- INREBIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Evaluate baseline thiamine levels prior to treatment initiation, do not initiate fedratinib in patients with thiamine deficiency. Replete thiamine prior to fedratinib initiation and during treatment if thiamine levels are low. |
| **Required Medical Information** | Diagnosis, Other therapies tried with treatment response, baseline thiamine level, baseline platelet level |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by Hematologist / Oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documented baseline platelet count of at least 50,000 per cubic milimeter. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INTERFERON ALPHA

## Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION
- PEGASYS SUBCUTANEOUS SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | FOR HEPATITIS C: PATIENT WEIGHT, GENOTYPE, HCV-RNA QUANTITY AND DATE OF TEST, PRESENCE OF CIRRHOSIS (Y/N), HISTORY OF ANEMIA OR DEPRESSION. HEPATITIS B: HBEAG STATUS, HBV DNA QUANTITY, AND ALT LEVEL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 2 YEARS FOR INDICATIONS OTHER THAN HEPATITIS C. HEPC APPROVALS FROM 12-48 WKS BASED ON DRUG REGIMEN |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# INVEGA IM

## Products Affected

- INVEGA HAFYERA INTRAMUSCULAR SYRINGE 1,092 MG/3.5 ML, 1,560 MG/5 ML
- INVEGA SUSTENNA INTRAMUSCULAR SYRINGE 117 MG/0.75 ML, 156 MG/ML, 234 MG/1.5 ML, 39 MG/0.25 ML, 78 MG/0.5 ML
- INVEGA TRINZA INTRAMUSCULAR SYRINGE 273 MG/0.88 ML, 410 MG/1.32 ML, 546 MG/1.75 ML, 819 MG/2.63 ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis and other treatments tried and outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a psychiatrist or mental health specialist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must have a reason oral paliperidone cannot be used. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IRESSA

## Products Affected

- *gefitinib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | GEFITINIB IS COVERED AS MONOTHERAPY |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ITOVEBI

## Products Affected

- ITOVEBI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IVERMECTIN

## Products Affected

- *ivermectin oral tablet 3 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by an infectious disease specialist or dermatologist. |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IVIG

## Products Affected

- BIVIGAM
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- GAMMAKED
- GAMMAPLEX
- GAMMAPLEX (WITH SORBITOL)
- GAMUNEX-C
- OCTAGAM
- PRIVIGEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and response to treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. Part B before Part D Step Therapy: SCIG will be reserved for members who cannot use IVIG due to poor access (on going access site issues unresolved by traditional means) - or - SCIG will be reserved for patients who continue to experience infusion reactions despite documented infusion rate adjustments and adequate pre-treatment. For Idiopathic thrombocytopenia purpura (ITP): trial and failure of oral corticosteroids at therapeutic dose (standard dosage of prednisone is 1 mg/kg/day) required. For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): trial and failure of oral corticosteroids at therapeutic dose (standard dosage of prednisone is 1-1.5 mg/kg/day) required. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# IWILFIN

## Products Affected

- IWILFIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# JAKAFI

## Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a hematologist, oncologist or transplant specialist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# JAYPIRCA

## Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must have a trial of either Calquence or Imbruvica prior to approval of Jaypirca. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# JOENJA

## Products Affected

- JOENJA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | FOR TREATMENT OF ACTIVATED PHOSPHOINOSITIDE 3 KINASE DELTA SYNDROME (APDS): CANNOT BE USED IN COMBINATION WITH AN IMMUNOSUPPRESSIVE MEDICATION |
| **Required Medical Information** | COVERAGE FOR ACTIVATED PHOSPHOINOSITIDE 3 KINASE DELTA SYNDROME (APDS) REQUIRES ALL OF THE FOLLOWING: 1. A DIAGNOSIS OF APDS WITH AN ASSOCIATED PI3K DELTA MUTATION, 2. DOCUMENTED VARIANT IN EITHER PIK3CD OR PIK3R1, AND 3. DOCUMENTED SYMPTOMS ASSOCIATED WITH APDS SUCH AS NODAL AND/OR EXTRANODAL LYMPHOPROLIFERATION, HISTORY OF REPEATED OTO-SINO-PULMONARY INFECTIONS AND/OR ORGAN DYSFUNCTION (E.G. LUNG, LIVER). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KALYDECO

## Products Affected

- KALYDECO ORAL GRANULES IN PACKET 13.4 MG, 25 MG, 5.8 MG, 50 MG, 75 MG
- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and the presence of one or more specific gene mutations that the drug is FDA approved to treat. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KERENDIA

## Products Affected

- KERENDIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for serum potassium greater than 5.0 mEq/L. |
| **Required Medical Information** | Diagnosis, prior drug treatments and outcomes. Potassium level within 30 days. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an endocrinologist, nephrologist or cardiologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | INITIATION: Documented diagnosis of chronic kidney disease (CKD) associated with diabetes mellitus, Type 2 (T2D). Documentation in the medical record that the patient is currently receiving the following standard of care background therapy with the requested agent: (a) a maximally tolerated dose of angiotensin converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), or a combination medication containing an ACE inhibitor or ARB therapy - AND - (b) an antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1) - OR - (c) according to the prescriber, the patient has contraindications to both ACE and ARB drug therapy. At baseline (prior to initiation of finerenone), (a) an estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73m2 AND - (b) serum potassium level less than or equal to 5.0 mEq/L. CONTINUATION: Serum potassium within 30 days. Demonstrated response of GFR with finerenone therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KISQALI

## Products Affected

- 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
- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KORLYM

## Products Affected

- *mifepristone oral tablet 300 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and outcome, HbA1c |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by endocrinologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Must have trial of ketoconazole therapy or have intolerance or contraindication to these medications. Must have failed surgery or not be a candidate for surgery. For continuation of therapy patient must show an improvement in HbA1c. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KOSELUGO

## Products Affected

- KOSELUGO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by oncology |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KRAZATI

## Products Affected

- KRAZATI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, diagnostic testing for muations, prior drug treatments and outcomes. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Diagnosis of KRAS G12C-mutated locally advanced or metastatic non1small cell lung cancer (NSCLC), or KRAS G12C-mutated locally advanced or metastatic colorectal cancer, as determined by an FDA-approved test, who have received at least one prior systemic therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# KUVAN

## Products Affected

- *sapropterin*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. BASELINE and FOLLOW-UP phenylalanine levels. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 2 MONTHS FOR INITIATION, 1 YEAR FOR CONTINUATION |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LAZCLUZE

## Products Affected

- LAZCLUZE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist/hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LENVIMA

## Products Affected

- 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)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LEUKINE

## Products Affected

- LEUKINE INJECTION RECON SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LIBTAYO

## Products Affected

- LIBTAYO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and/or failed, and response to prior therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LIDOCAINE TRANSDERMAL

## Products Affected

- *lidocaine topical adhesive patch,medicated 5 %*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LOKELMA

## Products Affected

- LOKELMA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of hyperkalemia, confirmed with laboratory test within the past month. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initiation, must have a failure, contraindication, or intolerance to sodium polystyrene sulfonate (SPS). For continuation, must show response to therapy as demonstrated by normal potassium levels and patient remains at high risk for recurrence of hyperkalemia. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LONSURF

## Products Affected

- LONSURF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LORBRENA

## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LUMAKRAS

## Products Affected

- LUMAKRAS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LYBALVI

## Products Affected

- LYBALVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for dementia-related psychosis. Not approved for patients using opioids. Not approved for patients undergoing acute opioid withdrawal. |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Psychiatrist or in consulation with psychiatrist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Demonstrated positive clinical response but with unacceptable weight gain while on single-agent olanzapine AND trial/failure of one other formulary atypical anti-psychotic (e.g., risperidone, aripiprazole, quetiapine, ziprasidone) titrated to maximum tolerated dose. Rationale for combination therapy in medical record. Patient does not have a known opioid use disorder nor is dependent on opioids for a chronic health condition. Prior to initiating LYBALVI when prescription history shows opioid fills within the last 30 days, prescriber attestation required to initiate olanzapine/samidorphine (LYBALVI): 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LYNPARZA

## Products Affected

- LYNPARZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# LYTGOBI

## Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MAVACAMTEN

## Products Affected

- CAMZYOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a cardiologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Must have an intolerance, contraindication, or treatment with at least one Non-vasodilating beta-blocker (e.g. metoprolol, propranolol or atenolol) AND one Non-dihydropyridine calcium channel blocker (e.g. verapamil, diltiazem) |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MEKINIST

## Products Affected

- MEKINIST ORAL RECON SOLN
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Wild-type BRAF melanoma |
| **Required Medical Information** | Diagnosis, Documentation of BRAF mutation, as detected using an FDA-approved test. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MEKTOVI

## Products Affected

- MEKTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must be used in combination with encorafenib. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# METHAMPHETAMINE

## Products Affected

- *methamphetamine*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies previously tried and failed, and response to treatment |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For the treatment of attention deficit disorder patient must have a trial of both methylphenidate and amphetamine/dextroamphetamine or rationale as to why these treatments are not suitable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MIRVASO

## Products Affected

- *brimonidine topical*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis and other treatments tried and outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For the treatment of acne rosacea: doxycycline (oral) and topical metronidazole. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MU-OPIOID RECEPTOR ANTAGONIST.

## Products Affected

- SYMPROIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Will not be approved for cancer related pain |
| **Required Medical Information** | Documented diagnosis of opiate induced constipation (non-cancer pain) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patient must have a trial of or contraindication to at least two different classes of laxative agents including bulk, osmotic, or stimulant laxatives. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# MYALEPT

## Products Affected

- MYALEPT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NAYZILAM

## Products Affected

- NAYZILAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a neurologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NERLYNX

## Products Affected

- NERLYNX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NEXLETOL

## Products Affected

- NEXLETOL
- NEXLIZET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to bempedoic acid (with or without ezetimibe). |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a cardiologist, endocrinologist, or physician who focuses on CV risk management and or lipid disorders. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For Primary hyperlipidemia: LDL of 190 or higher (not associated with ASCVD, HeFH, or HoFH), approve if tried one high-intensity statin therapy (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) and ezetimibe for at least 8 weeks and LDL remains 100 mg/dL or higher, unless statin intolerant. For Cardiovascular event risk, Statin intolerant with cardiovascular disease (CVD), or a high risk for a CVD event: History of atherosclerotic cardiovascular disease (ASCVD) or high risk of cardiovascular event. OR Established diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR atherosclerotic cardiovascular disease (ASCVD) with history of ONE of the following (for ASCVD): Myocardial infarction (MI) OR Acute Coronary Syndrome (ACS) OR Stable or unstable angina OR Thromboembolic stroke OR Transient ischemic attack (TIA) OR Peripheral arterial disease (PAD) OR Coronary or other arterial revascularization. . Patient has had a previous trial of or has a contraindication to a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) and LDL-C remains greater than 70 mg/dL with laboratory confirmation within the last 30 days. If intolerate of all statins, patient has had a trial of ezetimbe, unless contraindicated, and LDL-C remains greater than 70 mg/dL with laboratory confirmation within the last 30 days. Patient will continue taking the maximally tolerated statin (unless contraindicated) in combination with Nexletol or Nexlizet. |

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

# NINLARO

## Products Affected

- NINLARO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and/or failed, and treatment response.<br>Used in combination with Revlimid (lenalidomide) and dexamethasone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have an intolerance or contraindication to Velcade |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# NOXAFIL

## Products Affected

- *posaconazole oral suspension*
- *posaconazole oral tablet,delayed release (dr/ec)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, therapies tried, and outcome |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by infectious disease specialist, transplant specialist, hematologist, or oncologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | For the treatment of aspergillosis patient must have failure of, intolerance or contraindication to vorconizole OR rationale as to why vorconizole is not suitable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUBEQA

## Products Affected

- NUBEQA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to darolutamide. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or urologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | If metastatic disease patient must have a failure, intolerance, or contraindication to abiraterone (Zytiga) |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUCALA

## Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS RECON SOLN
- NUCALA SUBCUTANEOUS SYRINGE 100 MG/ML, 40 MG/0.4 ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For patients with asthma: allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count. For patients with eosinophilic granulomatosis with polyangiitis: documentation of diagnosis, prior therapies, and the outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a: pulmonologist, immunologist, allergist, rheumatologist, hematologist or otolaryngologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For patients with asthma: must be currently receiving inhaled and/or oral corticosteroid treatment, AND have a baseline eosinophil count of 300 cells/mcL or greater within previous 12 months or 150 cell/mcL within previous 6 weeks. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUEDEXTA

## Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by or in consultation with a neurologist, psychiatrist or geriatrician. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NUPLAZID

## Products Affected

- NUPLAZID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by or in consultation with a neurologist or psychiatrist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | must have a trial of or contraindication to quetiapine or clozapine. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# NURTEC

## Products Affected

- NURTEC ODT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For acute migraine : Unless contraindicated per the FDA label, a trial of at least one-month of a triptan. For chronic migraine: Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OCALIVA

## Products Affected

- OCALIVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and failed, and response to therapy, baseline alkaline phosphatase (ALP) level for initiation, and ALP levels after first 3 months of therapy and then yearly for continuation of therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Use in combination with ursodiol in patients with an inadequate biochemical response to treatment (elevated ALP levels) with ursodiol dosed at 13-15 mg/kg/day for at least 1 year, may be used as monotherapy in patients unable to tolerate ursodiol. Must show improvement in ALP levels for continuation. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ODOMZO

## Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has recurring disease following surgery or radiation OR patient is not a candidate for surgery or radiation therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or dermatologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OGSIVEO

## Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OJEMDA

## Products Affected

- OJEMDA ORAL SUSPENSION FOR RECONSTITUTION
- OJEMDA ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OJJAARA

## Products Affected

- OJJAARA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Members must have Myelofibrosis, Intermediate or high risk, primary or secondary, with anemia. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by an Oncologist or hematologist. |
| **Coverage Duration** | 5 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ONUREG

## Products Affected

- ONUREG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Do not substitute ONUREG for intravenous or subcutaneous azacitidine. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by an oncologist or hematologist oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORENCIA

## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other treatments tried and reasons for failure. Regular monitoring for TB required, both at baseline and during treatment. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY A RHEUMATOLOGIST |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For arthritic conditions, a 3 month trial at least one non-biologic DMARD (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine) and documented reason for failure (or contraindication). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORFADIN

## Products Affected

- *nitisinone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS AND WEIGHT |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY AN ENDOCRINOLOGIST, GASTROENTEROLOGIST, HEMATOLOGIST, METABOLIC SPECIALIST, OR NEPHROLOGIST |
| **Coverage Duration** | 6 months |
| **Other Criteria** | CLOSE MONITORING OF DISEASE MARKERS (ERYTHROCYTE PBG-SYNTHASE ACTIVITY, URINE 5-ALA, SUCCINYLACETONE) DURING THE FIRST 3 MONTHS OF TREATMENT TO ENSURE NORMALIZATION |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORGOVYX

## Products Affected

- ORGOVYX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Presribing limited to oncologist or urologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORKAMBI

## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has a diagnosis of cystic fibrosis (CF) AND Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene AND The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second [FEV1], decreased number of pulmonary exacerbations) |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ORSERDU

## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OTEZLA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by a Rheumatologist or Dermatologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# OXERVATE

## Products Affected

- OXERVATE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an ophthalmologist |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PALYNZIQ

## Products Affected

- PALYNZIQ SUBCUTANEOUS SYRINGE 10 MG/0.5 ML, 2.5 MG/0.5 ML, 20 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior treatments, and outcome. Baseline and follow up phenylalanine (Phe) concentrations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Must have phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management, and a failure, contraindication, or intolerance to Kuvan. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PANRETIN

## Products Affected

- PANRETIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PDE-5 INHIBITORS FOR PAH

## Products Affected

- *sildenafil (pulmonary arterial hypertension) oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, right heart cath results. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | For PAH:  prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Sildenafil must be tried prior to the use of the other drugs included in these criteria, unless using ambrisentan (Letairis) plus tadalafil for treatment-naive, WHO functional class II or III PAH. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PEMAZYRE

## Products Affected

- PEMAZYRE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or gastroenterologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documentation of a susceptible fibroblast growth factor receptor 2 fusion or other genetic rearrangement (as detected by an FDA-approved test). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PHENOBARBITAL

## Products Affected

- *phenobarbital*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for use in sedation/insomnia. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patients aged less than 65 years are approved. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For the treatment of seizures, approve only if the patient is currently taking phenobarbital. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PIQRAY

## Products Affected

- PIQRAY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Breast Cancer. Approve if the patient meets the following criteria (A, B, C, and D,): A)The patient has advanced or metastatic hormone receptor (HR)-positive disease AND B)The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND C)The patient has PIK3CA-mutated breast cancer as detected by an approved test AND D)The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# POMALYST

## Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including serum creatinine, and serum calcium within 6 months. Documentation of prior therapies and responses to treatment must be provided. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PROLIA

## Products Affected

- PROLIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including serum creatine and, documentation of prior therapies and responses to treatment must be provided. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed or in consultation with Endocrinologist, Hematologist/Oncologist, Obstetrician/Gynecologist, Rheumatologist or Urologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For treatment of postmenopausal osteoporosis / treatment of osteoporosis in men [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: (1) has had inadequate response after 6 months of therapy with an oral bisphosphonate or (2) had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate or (3) the patient cannot take an oral bisphosphonate because (s)he cannot swallow or has difficulty swallowing, cannot remain in an upright position, or has a pre-existing GI medical condition - AND - the patient has tried an IV bisphosphonate (e.g., ibandronate or zoledronic acid). A T-score or DEXA scan within 1 year must be submitted for review for all requests. Part B before Part D Step Therapy. Approve if the patient has severe chronic kidney disease (e.g., creatinine clearance less than 35 mL/min). Approve for treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer or receiving adjuvant AI therapy for breast cancer. For treatment of glucocorticoid induced osteoporosis (GIO), approve if the patient has tried one oral bisphosphonate OR patient cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing, or the patient cannot remain in an upright position post oral bisphosphonate administration, or |

| PA Criteria | Criteria Details |
|---|---|
| | has a pre-existing GI medical condition (e.g., esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR patient has tried zoledronic acid (Reclast), OR patient has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# PROMACTA

## Products Affected

- PROMACTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | For ITP, eltrombopag should only be used if the degree of thrombocytopenia and clinical condition increase the risk for bleeding. For chronic hepatitis C, eltrombopag should only be used if the degree of thrombocytopenia prevents initiation of or limits the ability to maintain interferon-based therapy. Eltrombopag is not indicated for the treatment of myelodysplastic syndromes. |
| **Required Medical Information** | Diagnosis, other therapies tried and outcome.  Platelet count. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PULMONARY HYPERTENSION

## Products Affected

- *ambrisentan*
- *bosentan*
- OPSUMIT
- ORENITRAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Confirmation of diagnosis of pulmonary arterial hypertension (WHO GROUP 1). |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a pulmonologist or cardiologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | PAH (WHO Group 1) diagnosis confirmed by a right heart catheterization to ensure appropriate medical assessment. For new starts in the Treatment Naive patient: must initiate treatment with dual therapy with tadalafil and ambrisentan, unless intolerant or contraindicated. For these drugs: bosentan, macitentan, treprostnil: must show documentation of prior drug treatment. Note: patients who are already established on any therapy and clinically responsive and stable, a step-back to dual therapy is not required. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PURIXAN

## Products Affected

- PURIXAN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and prior treatment with oral mercaptopurine tablet and response to treatment including if contraindicated. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | prescriber must be a oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have a intolerance, contraindication, or medical reason why mercaptopurine tablet is not acceptable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PYRUKYND

## Products Affected

- PYRUKYND ORAL TABLET
- PYRUKYND ORAL TABLETS,DOSE PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a hemoatologist or oncologist |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Continuation of therapy  is dependant on response to therapy, determined by treating physician. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# QINLOCK

## Products Affected

- QINLOCK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to ripretinib. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a oncologist or gastroenterologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For initiation, documentation of prior treatment with three or more kinase inhibitors, including imatinib. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RADICAVA

## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or prescriber expertise with treating ALS |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of Juxtapid or Praluent. |
| **Required Medical Information** | Current LDL-C (within 30 days of request), documentation of prior statin drug(s) and/or ezetimibe previously tried including dosage and response to therapy such as adverse event history (for example muscle pain), and/or inadequate reduction of LDL-C (provide lab value). Maximally tolerated statin therapy may mean zero tolerance for those patients who cannot tolerate a statin. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| **Coverage Duration** | Approve for 3 years |
| **Other Criteria** | Hyperlipidemia with HeFH - approve if: (1) diagnosis of HeFH - AND - (2) tried ezetimibe and ONE high intensity statin (e.g., atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher, unless patient is statin intolerant defined by experiencing statin-related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin, and during both trials the symptoms resolved upon discontinuation. For hyperlipidemia with ASCVD, approve if: (1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure - AND - (2) tried ezetimibe and ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher, unless patient is statin intolerant (defined above). For HoFH, approve if: (1) has one of the following: (a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR (b) untreated LDL greater than 500 mg/dL (prior to treatment), OR (c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such |

| PA Criteria | Criteria Details |
|---|---|
| | as Repatha or Juxtapid), OR (d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND - (2) tried ezetimibe and ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). For primary hyperlipidemia with LDL of 190 or higher (not associated with ASCVD, HeFH, or HoFH), approve if tried one high-intensity statin therapy (defined above) and ezetimibe for at least 8 weeks and LDL remains 100 mg/dL or higher, unless statin intolerant (defined above). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RETEVMO

## Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a oncologist, pulmonologist or endocrinologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For initiation, documentation of the presence of a RET gene fusion (with non-small cell lung cancer or thyroid cancer) or specific RET gene mutation (medullary thyroid cancer) in tumor specimens or plasma. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REVCOVI

## Products Affected

- REVCOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documented diagnosis of adenosine deaminase (ADA) deficiency, IgA, IgM and IgG levels, CBC, and the prescence of mutations in the ADA gene at 20q13.11 |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an immunologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REVLIMID

## Products Affected

- *lenalidomide*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and previous therapies or drug regimens tried. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | MCL-approve if the patient meets one of the following 1) Pt has tried two prior therapies or therapeutic regimens OR 2) Pt has tried one prior therapy or therapeutic regimen and cannot take Velcade according to the prescribing physician. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen. Myelofibrosis-approve if the pt has tried one other therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REVUFORJ

## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REZDIFFRA

## Products Affected

- REZDIFFRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patients with decompensated cirrhosis |
| **Required Medical Information** | Medical records supporting the request, including documentation of metabolic dysfunction-associated steatohepatitis (MASH) OR nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) and liver function test (AST/ALT). |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a gastroenterologist or hepatologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | F2/F3 fibrosis confirmed by biopsy OR non-invasive tests (Ex: Fib4, Fibroscan). Prescriber attestation that patient has received counseling on diet and exercise. Documentation of failure with pioglitazone. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REZLIDHIA

## Products Affected

- REZLIDHIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by hematologist/oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# REZUROCK

## Products Affected

- REZUROCK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be prescribed by oncologist, hematologist, or transplant specialist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RINVOQ

## Products Affected

- RINVOQ
- RINVOQ LQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a rheumatologist, dermatologist, or gastroenterologist |
| **Coverage Duration** | For Ulcerative Colitis, 8 weeks for 45 mg daily. 3 years for all other indications |
| **Other Criteria** | Prior to receiving treatment with Rinvoq for arthritis related conditions, the patient must have trial and failure of at least one non-biologic DMARDs, including but not limited to methotrexate, hydroxychloroquine and sulfasalazine, azathioprine for at least three months or have a contraindication. For atopic dermatitis: a trial on at least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus). For inflammatory bowel disease (CD and UC), the patient must have an inadequate response or intolerance to a tumor necrosis factor blockers. Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ROZLYTREK

## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist. |
| **Coverage Duration** | 5 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RUBRACA

## Products Affected

- RUBRACA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | OVARIAN CANCER (epithelial ovarian, fallopian tube or primary peritoneal): Diagnosis of advanced ovarian cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test. Patients are in a complete or partial response to platinum-based chemotherapy. Maintenance Therapy-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. PROSTATE CANCER: Diagnosis of advanced metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test. History of failure, contraindication, or intolerance to androgen receptor-directed therapy and a taxane-based chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# RYDAPT

## Products Affected

- RYDAPT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test, used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All indications: Prescribed by or in consultation with a hematologist, allergist or oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SAMSCA

## Products Affected

- *tolvaptan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, patient has a serum sodium less than 125 mEq/L at baseline, OR member has less marked hyponatremia (serum sodium less than 135 mEq/L at baseline) AND is symptomatic (e.g. nausea, vomiting, headache, lethargy, confusion, and baseline LFTs). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a specialist appropriate to the disease state sucha as an endocrinologist or nephrologist. |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Patient must have documented failure of two other therapies (e.g. fluid restriction, furosemide, demeclocycline). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SCEMBLIX

## Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by oncologist or hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIGNIFOR

## Products Affected

- SIGNIFOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and other treatments tried and failed. Documentation: of surgery with response (if performed), or when surgery is not a treatment option. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an endocrinologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SIRTURO

## Products Affected

- SIRTURO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and/or failed. ECG and liver function tests are required at baseline and at intervals as specified in the FDA prescribing information to monitor for potentially severe adverse events. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a infectious disease specialist |
| **Coverage Duration** | 24 weeks |
| **Other Criteria** | Drug therapy must be directly observed. Use of Sirturo is reserved for MDR-TB where other treatment options cannot be used for safety or efficacy reasons. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SKYCLARYS

## Products Affected

- SKYCLARYS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis and Confirmation of diagnosis via genetic testing revealing two pathogenic mutations of the frataxin (FXN) gene. Obtain alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, B-type natriuretic peptide (BNP), and lipid parameters. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a Neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SKYRIZI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by a gastroenterologist, dermatologist, or rheumatologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate. For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (methotrexate, sulfasalazine, azathioprine). For inflammatory bowel disease (CD), must have trial of or contraindication to at least one non-biologic conventional therapy, including but not limited to sulfasalazine, azathioprine, or methotrexate. For UC: patient has tried a systemic therapy (e.g., 6-mercaptopurine, azathioprine, CSA, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SPRITAM

## Products Affected

- SPRITAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, therapies tried, and outcome |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by Neurologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Rationale as to why generic levetiracetam is not suitable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SPRYCEL

## Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST OR HEMATOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have a failure, intolerance or contraindication to imatinib. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies, and result of prior therapy. TB test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by gastroenterologist, dermatologist or rheumatologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate. For psoriasis and psoriatic arthritis, 90 mg dosing requires demonstration of treatment failure of 45 mg for 16 weeks and patient weight greater than 100kg. For inflammatory bowel disease (CD and UC), must have trial of or contraindication to at least one non-biologic conventional therapy, including but not limited to sulfasalazine, mesalamine, azathioprine, or methotrexate. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# STIVARGA

## Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis,  LFT lab test results are needed for continuation treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SUTENT

## Products Affected

- *sunitinib malate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS, PRIOR THERAPIES, AND TREATMENT RESPONSE. DOCUMENATION OF FAILURE OF IMATINIB FOR PATIENTS WITH GIST. DOCUMENTATION OF FAILURE OF VOTRIENT FOR PATIENTS WITH RENAL CELL CARCINOMA. IF NO PREVIOUS FAILURE, RATIONALE AS TO WHY PREFERRED AGENT CANNOT BE USED |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | GIST PATIENTS REQUIRE A FOLLOW-UP CT SCAN BETWEEN 8 AND 12 WEEKS. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYMDEKO

## Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of CF AND homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patients genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. FEV1 at baseline and continuation, baseline LFT and continuation, review for drug interactions CYP3A inducers |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by a pulmonologist or doctor specializing in cystic fibrosis |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations) |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYMLIN

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | GASTROPARESIS OR USE OF DRUGS TO STIMULATE GASTROINTESTINAL MOTILITY |
| **Required Medical Information** | HBA1C AND CURRENT DIABETES MEDICATIONS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 YEAR |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# SYMPAZAN

## Products Affected

- SYMPAZAN ORAL FILM 10 MG, 20 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have failure, intolerance, or contraindication to generic clobazam |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TABRECTA

## Products Affected

- TABRECTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by an oncologist or pulmonologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documentation of a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TADALAFIL

## Products Affected

- *tadalafil oral tablet 5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Erectile Dysfunction |
| **Required Medical Information** | Documented diagnosis of BPH |
| **Age Restrictions** | n/a |
| **Prescriber Restrictions** | n/a |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Confirmation of diagnosis with appropriate testing. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a cardiologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAFINLAR

## Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Wild-type BRAF melanoma |
| **Required Medical Information** | Diagnosis, Documentation of BRAF mutation, as detected using an FDA-approved test. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAGRISSO

## Products Affected

- TAGRISSO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis supported with an approved test for the detection of mutations named in FDA label found in tumor or plasma specimens. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TALZENNA

## Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TARCEVA

## Products Affected

- *erlotinib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TARGRETIN

## Products Affected

- *bexarotene topical*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. If continuation, response to bexarotene. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribing limited to a specialist in dermatology, hematolgy, or oncology. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Documentation that the patient has refractory or persistent cutaneous T-cell lymphoma (stage IA and IB) or who has not tolerated other therapies |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TASIGNA

## Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS, OTHER THERAPIES TRIED AND FAILED, RESPONSE TO TREATMENT, POTENTIAL DRUG INTERACTIONS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by oncologist or hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have a failure, intolerance or contraindication to imatinib and Sprycel. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAVNEOS

## Products Affected

- TAVNEOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior treatments, response to therapy |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by hematologist, rheumatologist, neurologist, nephrologist, or immunologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Patient must have tried and failed two of the following: azathioprine, methotrexate, mycophenolate, rituximab, or cyclophosphamide |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAZORAC

## Products Affected

- *tazarotene topical cream*
- *tazarotene topical gel*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 YEAR |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TAZVERIK

## Products Affected

- TAZVERIK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribing limited to a hematologist/oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TEPMETKO

## Products Affected

- TEPMETKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by an oncologist or pulmonologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For NSCLC:  confirmation of genertic alteration with biomarker testing for mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TESTOSTERONE

## Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as |

| PA Criteria | Criteria Details |
|---|---|
| | an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TIBSOVO

## Products Affected

- TIBSOVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRANSMUCOSAL IR FENTANYL

## Products Affected

- *fentanyl citrate buccal lozenge on a handle 1,200 mcg, 200 mcg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | NOT approved for patients who are NOT tolerant to opioid drug treatment - AND - are NOT receiving long-acting opioids |
| **Required Medical Information** | Diagnosis and prior drug treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Documentation that shows prior use of two formulary short-acting opioid analgesics such as oxycodone, morphine, or hydromorphone as immediate-release (IR) tablet formulations or oral solution. Explanation of treatment failure or product intolerance must also explain why this unique method of administration is medically necessary and why a traditional short-acting oral opiate medication cannot be continued. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRELSTAR DEPOT, TRELSTAR LA

## Products Affected

- TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRETINOIN

## Products Affected

- *tretinoin topical*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for cosmetic use. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRIENTINE

## Products Affected

- *trientine oral capsule 250 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried and the outcome |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or hepatatologist. |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Must have a failure, contraindication, or intolerance to penicillamine. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TRUQAP

## Products Affected

- TRUQAP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Breast cancer, Locally advanced or metastatic, hormone receptor-positive, HER2-negative, with one or more PIK3CA/AKT1/PTEN-alteration |
| **Age Restrictions** | Member is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TUKYSA

## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | For initiation, documentation of human epidermal growth factor receptor 2 (HER2) testing. Documentation of one or more prior anti-HER2-based regimens in the metastatic setting. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TURALIO

## Products Affected

- TURALIO ORAL CAPSULE 125 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis: symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery in adults. If continuation, prior response to pexidartinib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TYKERB

## Products Affected

- *lapatinib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# TYMLOS

## Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for a cumulative lifetime duration of abaloparatide and any other parathyroid hormone therapy (eg, teriparatide) of more than 2 years. Not approved for combination therapy of a PTH/PTHrP analog in combination with other osteoporosis agents. |
| **Required Medical Information** | Diagnosis, fracture history, prior therapy used and response to prior therapy. Required pretreatment testing: DXA, if not performed in the past two years: serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D), and, 24-hour urine calcium, creatinine (or fasting specimen for calcium/creatine ratio) to evaluate for baseline hypercalciuria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an endocrinologist. |
| **Coverage Duration** | 2 years |
| **Other Criteria** | Documentation of a trial on an oral bisphosphonate, or, if GI intolerant of oral bisphosphonates, use of a parenteral bisphosphonate - AND - a trial on denosumab. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# UBRELVY

## Products Affected

- UBRELVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Excluded for migraine prevention. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Unless contraindicated per the FDA label, a trial of at least one-month of a triptan. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# UCERIS

## Products Affected

- *budesonide oral tablet,delayed and ext.release*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for maintenance of remission or in patients with severe disease (UCDAI score = 10) |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a gastroenterology specialist |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# UREA CYCLE DISORDER

## Products Affected

- RAVICTI
- *sodium phenylbutyrate oral powder*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VALCHLOR

## Products Affected

- VALCHLOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VALTOCO

## Products Affected

- LIBERVANT
- VALTOCO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribing limited to a neurologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VANFLYTA

## Products Affected

- VANFLYTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FLT3 internal tandem duplication (ITD)-positive) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test, used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation and as maintenance monotherapy following consolidation chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VELTASSA

## Products Affected

- VELTASSA ORAL POWDER IN PACKET 16.8 GRAM, 25.2 GRAM, 8.4 GRAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Evidence of episodes of moderate to severe hyperkalemia (serum potassium level = 5.1 mEq/L) requiring discontinuation or dose reduction of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and/or aldosterone antagonists AND receives medication regimen that allows for practical administration of Veltassa 3 hours before or 3 hours after other oral medications |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Member is 18 years of age and older, prior use of sodium polystryrene (SPS) and sodium zirconium cyclosilicate (Lokelma). Members 12 to 17 years of age, prior use of sodium polystryrene (SPS). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VENCLEXTA

## Products Affected

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VEOZAH

## Products Affected

- VEOZAH

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies tried, and outcome. Baseline hepatic function (including ALT, AST, and serum bilirubin [total and direct] before initiating therapy) |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Patients must have an inadequate response, contraindication, or intolerance to two different medications such as conjugated estrogens, Venlafaxine, gabapentin, or clonidine. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VERZENIO

## Products Affected

- VERZENIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | NA |
| **Required Medical Information** | Documentation of diagnosis, and LFTs. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by oncology |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VICTOZA

## Products Affected

- *liraglutide*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not covered for weight loss |
| **Required Medical Information** | For Liver Disease: Medical records supporting diagnosis of Liver Disease (MAFLD/MASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), confirmed by biopsy OR non-invasive tests (Ex: Fib4, Fibroscan) and liver function test (AST/ALT). Type 2 Diabetes: Documented diagnosis of Type 2 diabetes. Submitted A1C from past 6 months. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Liver Disease: Must be prescribed by or in consultation with a gastroenterologist or hepatologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Liver Disease (MAFLD/MASH): Trial and failure with pioglitazone. Diabetes: Member has tried and failed metformin ER (at maximum tolerated doses for 3 months), and one other antidiabetic drug from a different class. Members who are adolescents 10 years or older with type 2 diabetes need to try only one antidiabetic drug. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VITRAKVI

## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VIZIMPRO

## Products Affected

- VIZIMPRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VONJO

## Products Affected

- VONJO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | NA |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by oncology and hematology |
| **Coverage Duration** | 3 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VORANIGO

## Products Affected

- VORANIGO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Medical records supporting the request, including evidence of IDH1 or IDH2 mutation. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist/hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VORICONAZOLE

## Products Affected

- *voriconazole intravenous*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for topical use such as Foot Bath, Nasal Rinse, Mouthwash, etc. applications. |
| **Required Medical Information** | Medically accepted indication. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VOTRIENT

## Products Affected

- *pazopanib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# VOWST

## Products Affected

- VOWST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medical records supporting the request, including documentation of positive clostridioides difficile infection (CDI) test and at least 2 recurrent episodes of CDI (3 or more total CDI episodes) after failure of treatment with fidaxomicin and Rebyota. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist. |
| **Coverage Duration** | 1 year. Limited to 1 treatment course (12 capsules over 3 days). |
| **Other Criteria** | n/a |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | Yes |

# WAINUA

## Products Affected

- WAINUA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Polyneuropathy due to amyloidosis, Hereditary transthyretin-mediated. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by a neurologist. |
| **Coverage Duration** | 3 years. |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# WEILREG

## Products Affected

- WELIREG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# WINREVAIR

## Products Affected

- WINREVAIR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | n/a |
| **Required Medical Information** | Diagnosis. Medical records supporting the request. Confirmation of diagnosis of pulmonary arterial hypertension (WHO GROUP 1). Prior therapies used and responses to treatments. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Patient is currently receiving at least two other PAH therapies from the following different pharmacologic categories: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins OR Patient is currently receiving at least one other PAH therapy and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XATMEP

## Products Affected

- XATMEP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and prior treatment with methotrexate tablets or vials for injection and response to treatment including if contraindicated. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or rheumatologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Must have a intolerance, contraindication, or medical reason why methotrexate tablets or vials for injection are not acceptable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XCOPRI

## Products Affected

- XCOPRI MAINTENANCE PACK
- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- XCOPRI TITRATION PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not approved for patients with familial short QT syndrome. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescription must be written by a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XDEMVY

## Products Affected

- XDEMVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For treatment of symptomatic Demodex blepharitis (DB). Symptoms defined as redness, inflammation, missing or misdirected eyelashes, itching along the eyelid base, and the presence of collarettes. |
| **Age Restrictions** | Member is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Diagnosed by an ophthalmologist. |
| **Coverage Duration** | 6 weeks |
| **Other Criteria** | Diagnosis must include: eyelash epilation for examination by light microscopy for identification and confirmation of Demodex infestation OR collarettes that are visible on slit lamp examination. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XELJANZ

## Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, response to prior therapy. Documentation of negative TB test. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Prescribed by a specialist appropriate to the disease state, such as a rheumatologist or gastroenterologist. |
| **Coverage Duration** | 3 year , Xelzanz XR 22 mg - 16 weeks |
| **Other Criteria** | Prior to receiving treatment with Xeljanz for ARTHRITIS-RELATED conditions, the patient must have trial of, or contraindication to, at least one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling. Prior to receiving treatment with Xeljanz XR 22 mg for an ULCERATIVE COLITIS condition, the patient must have an inadequate response or intolerance to tumor necrosis factor blockers (including but not limited to adalimumab). Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XERMELO

## Products Affected

- XERMELO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, Somatuline Depot) for at least 3 months AND used in combination with SSA therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For continuation of therapy-Documentation of a positive clinical response to Xermelo therapy AND Xermelo will continue to be used in combination with SSA therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XGEVA

## Products Affected

- XGEVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by oncologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XIFAXAN

## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not covered for PROPHYLAXIS of traveler's diarrhea. For TREATMENT of traveler's diarrhea, not covered for diarrhea due to pathogens other than E. coli, and, not covered for diarrhea complicated by fever or blood in the stool. |
| **Required Medical Information** | Small bowel bacterial overgrowth syndrome (SIBO): The patients diagnosis has been confirmed by ONE of the following: A) quantitative culture of upper gut aspirate, B) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test). OR The patient is experiencing a recurrence of small intestinal bacterial overgrowth (SIBO) after completion of a successful course of the requested drug. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months for all medically accepted indications, excepting 2 years for hepatic encephalopathy. |
| **Other Criteria** | For hepatic encephalopathy: treatment failure, intolerance, or contraindication to lactulose. For travelers diarrhea: treatment failure, intolerance, or contraindication to a fluoroquinolone (such as ciprofloxacin) and azithromycin. For IBS-D: treatment failure, intolerance, or contraindication to at least two of these drugs: loperamide, dicyclomine or diphenoxylate/atropine. For recurrent C. difficile: treatment failure, intolerance, or contraindication to vancomycin. For SIBO symptoms that do not respond to a 7- to 10-day therapeutic trial of ONE of the following, unless the treatment is medically inadvisable or the patient has a history of intolerance to the treatment: metronidazole. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

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

# XOLAIR

## Products Affected

- XOLAIR SUBCUTANEOUS AUTO-INJECTOR
- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For asthma: weight, IgE level at baseline, baseline FEV1, FEV1 following bronchodilator, medication history, ER visits, and hospitalizations. Evidence of a positive skin test or in-vitro reactivity to a perennial aeroallergen. For uticaria: documentation of persistence of hives associated with itching and prior treatments with outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a pulmonologist, immunologist, allergist, dermatologist or otolaryngologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Moderate to severe persistent asthma approve if the patient meets criteria 1 and 2: 1) patient has received combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy. For chronic idiopathic urticaria (CIU), approve if the patient has documented CIU for at least 6 weeks AND failure, intolerance, or contraindication to cyclosporine and montelukast. For |

| PA Criteria | Criteria Details |
|---|---|
| | continuation of asthma treatment - The patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For continuation of CIU treatment - The patient must have responded to therapy as determined by the prescribing physician. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XOSPATA

## Products Affected

- XOSPATA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XPOVIO

## Products Affected

- XPOVIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XTANDI

## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to enzalutamide. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by an oncologist or urologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must undergo evaluation of seizure risk. For metastatic castration resistant prostate cancer (CRPC) -- OR -- metastatic castration-sensitive prostate cancer (CSPC), patient must have a failure, intolerance, or contraindication to abiraterone (Zytiga) prior to initiation of therapy with enzalutamide (Xtandi). |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# XYREM

## Products Affected

- SODIUM OXYBATE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Not to be used in patients concurrently using alcohol or sedative-hypnotic agents |
| **Required Medical Information** | Diagnosis, including sleep study. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescription must be written by a sleep medicine specialist or neurologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Dosing approved up to 9 grams per day |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZEJULA

## Products Affected

- ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZELBORAF

## Products Affected

- ZELBORAF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | PATIENTS WITH WILD-TYPE BRAF MELANOMA, PREGNANCY |
| **Required Medical Information** | FOR METASTATIC MELANOMA: DOCUMENTATION OF DIAGONSIS AND BRAF V600E MUTATION AS DETECTED USING AN FDA-APPROVED TEST. FOR ERDHEIM-CHESTER DISEASE: DOCUMENTATION OF DIAGNOSIS AND BRAF V600 MUTATION. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | PERFORM DERMATOLOGICAL EVALUATIONS PRIOR TO INITIATION OF THERAPY AND EVERY 2 MONTHS WHILE ON THERAPY TO MONITOR FOR NEW PRIMARY MELANOMAS. MONITOR LIVER FUNCTION TESTS PRIOR TO INITIATION OF THERAPY AND AS CLINICALLY INDICATED THEREAFTER. MONITOR ECGs PRIOR TO INITIATION OF THERAPY, AT DAY 15, THEN MONTHLY, AND EVERY 3 MONTHS THEREAFTER.MONITOR PATIENTS FOR OPHTHALMOLOGIC REACTIONS AS CLINICALLY INDICATED. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZILBRYSQ

## Products Affected

- ZILBRYSQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis. Members must have confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | prescribed by a neurologist. |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Patient must have an inadequate response, contraindication, or intolerance to two different immunosuppressant therapies: Azathioprine, mycophenolate, methotrexate, cyclosporine, or tacrolimus. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZOLINZA

## Products Affected

- ZOLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Must be prescribed by an oncologist/hematologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZONISADE

## Products Affected

- ZONISADE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous treatments, and response therapy |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Must have a intolerance, contraindication, or medical reason the capsule are not acceptable. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZTALMY

## Products Affected

- ZTALMY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis. |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | Must be prescribed by a neurologist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZURZUVAE

## Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Postpartum Depression |
| **Age Restrictions** | Beneficiary is of appropriate age for use per FDA prescribing information. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZYDELIG

## Products Affected

- ZYDELIG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY. FOR PATIENTS WITH CLL , DOCUMENTATION OF PRIOR TREATMENT WITH IMBRUVICA. IF NO PREVIOUS FAILURE, RATIONALE AS TO WHY PREFERRED AGENT CANNOT BE USED |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST OR HEMATOLOGIST |
| **Coverage Duration** | 5 years |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# ZYPREXA RELPREVV

## Products Affected

- ZYPREXA RELPREVV INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION 210 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis and other treatments tried and outcome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by a psychiatrist or mental health specialist. |
| **Coverage Duration** | 5 years |
| **Other Criteria** | Patient must have a reason Olanzapine oral cannot be used. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Part B Prerequisite** | No |

# PART B VERSUS PART D

## Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine solution 100 mg/ml (10 %), 200 mg/ml (20 %)*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml, 5 mg/ml*
- *amphotericin b injection recon soln 50 mg*
- *arformoterol inhalation solution for nebulization 15 mcg/2 ml*
- *azathioprine oral tablet 100 mg, 50 mg, 75 mg*
- *bleomycin injection recon soln 15 unit, 30 unit*
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- CLINIMIX 5%/D15W SULFITE FREE INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX 4.25%/D10W SULF FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 4.25%/D5W SULFIT FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 5%-D20W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 5 %
- *cromolyn inhalation solution for nebulization 20 mg/2 ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- CYCLOPHOSPHAMIDE ORAL TABLET 25 MG, 50 MG
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- ENGERIX-B (PF) INTRAMUSCULAR SUSPENSION 20 MCG/ML
- ENGERIX-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/ML
- ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE 10 MCG/0.5 ML
- *everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- *formoterol fumarate inhalation solution for nebulization 20 mcg/2 ml*
- *gengraf oral capsule 100 mg, 25 mg*
- *gengraf oral solution 100 mg/ml*
- *granisetron hcl oral tablet 1 mg*
- HEPLISAV-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/0.5 ML
- IMOVAX RABIES VACCINE (PF) INTRAMUSCULAR RECON SOLN 2.5 UNIT
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution for nebulization 0.5 mg-3 mg(2.5 mg base)/3 ml*
- *levalbuterol hcl inhalation solution for nebulization 0.31 mg/3 ml, 0.63 mg/3 ml, 1.25 mg/0.5 ml, 1.25 mg/3 ml*
- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension for reconstitution 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*

- *mycophenolate sodium oral tablet,delayed release (dr/ec) 180 mg, 360 mg*
- *ondansetron hcl oral solution 4 mg/5 ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet,disintegrating 4 mg, 8 mg*
- *pentamidine inhalation recon soln 300 mg*
- PLENAMINE INTRAVENOUS PARENTERAL SOLUTION 15 %
- *premasol 10 % intravenous parenteral solution 10 %*
- PROGRAF ORAL GRANULES IN PACKET 0.2 MG, 1 MG
- PROSOL 20 % INTRAVENOUS PARENTERAL SOLUTION
- PULMOZYME INHALATION SOLUTION 1 MG/ML
- RABAVERT (PF) INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION 2.5 UNIT
- RECOMBIVAX HB (PF) INTRAMUSCULAR SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5 ML
- RECOMBIVAX HB (PF) INTRAMUSCULAR SYRINGE 10 MCG/ML, 5 MCG/0.5 ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- *tobramycin in 0.225 % nacl inhalation solution for nebulization 300 mg/5 ml*
- *tobramycin inhalation solution for nebulization 300 mg/4 ml*
- *travasol 10 % intravenous parenteral solution 10 %*
- TROPHAMINE 10 % INTRAVENOUS PARENTERAL SOLUTION 10 %
- YUPELRI INHALATION SOLUTION FOR NEBULIZATION 175 MCG/3 ML

## Details

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

**Index**

**C**



**D**



**E**