**Prior Authorization Requirements**
**Effective April 1, 2019**

# ACROMEGALY THERAPY

## Products Affected

- Somatuline Depot subcutaneous syringe 120 mg/0.5 mL, 60 mg/0.2 mL, 90 mg/0.3 mL
- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (FOR SOMAVERT, IGF-1 LEVELS AND LIVER TESTS SHOULD BE MONITORED AND SOMAVERT SHOULD BE DISCONTINUED IF LFTS ARE GREATER THAN 5 TIMES THE UPPER LIMIT OF NORMAL), AND DOCUMENTATION OF PREVIOUS THERAPIES (FOR ACROMEGALY- DOCUMENTATION OF FAILURE OF SURGERY, RADIATION, AND MEDICAL TREATMENT IS REQUIRED- EXAMPLES OF MEDICAL TREATMENT IS OCTREOTIDE.) |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | FOR ACROMEGALY, SOMATULINE DEPOT OR SOMAVERT MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST. FOR GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS, SOMATULINE DEPOT MUST BE PRESCRIBED BY AN ONCOLOGIST. |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF ACROMEGALY IN PATIENTS WHO HAVE HAD FAILURE OF SURGERY, RADIATION AND MEDICAL RX (EXAMPLE:OCTREOTIDE). SOMAVERT SPECIFIC- IGF-1 LEVELS AND LIVER TESTS SHOULD BE MONITORED AND SOMAVERT SHOULD BE DISCONTINUED IF LFT'S ARE GREATER THAN 5 TIMES UPPER LIMIT OF NORMAL. REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# ACTEMRA

## Products Affected

- Actemra ACTPen
- Actemra subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | FOR DX OF RHEUMATOID ARTHRITIS OR GIANT CELL ARTERITIS, PATIENT MUST BE 18 YEARS OF AGE OR OLDER. FOR DX OF JUVENILE IDIOPATHIC ARTHRITIS (SYSTEMIC OR POLYARTICULAR) OR CYTOKINE RELEASE SYNDROME, PATIENT MUST BE 2 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A RHEUMATOLOGIST, OPHTHALMOLOGIST, NEUROLOGIST, ONCOLOGIST OR HEMATOLOGIST |
| **Coverage Duration** | TWO YEARS FOR RA, JIA, AND GIANT CELL ARTERITIS. 6 MONTHS FOR USE WITH CAR-T CELL THERAPY |
| **Other Criteria** | ACTEMRA WILL BE COVERED FOR A DIAGNOSIS OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS FOR PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR. IF APPROVED FOR INITIAL THERAPY, INITIAL DOSING WILL BE LIMITED TO 4MG/KG EVERY 4 WEEKS. BASED ON CLINICAL RESPONSE, DOSE CAN BE INCREASED TO 8MG/KG BUT THE TOTAL DOSE CANNOT EXCEED 800MG. ACTEMRA WILL BE APPROVED FOR JUVENILE IDIOPATHIC ARTHRITIS (SYSTEMIC OR POLYARTICULAR) FOR PATIENTS WITH DOCUMENTATED FAILURE TO BOTH OF THE FOLLOWING ALTERNATIVES: ENBREL AND HUMIRA. IF APPROVED FOR INITIAL THERAPY, INITIAL DOSING WILL BE LIMITED TO 10MG/KG EVERY 4 WEEKS FOR PATIENTS UNDER 30KG, AND 8MG/KG EVERY 4 WEEKS FOR PATIENTS 30KG AND OVER. FOR |

| PA Criteria | Criteria Details |
| --- | --- |
| | SJRI DOSING IS EVERY TWO WEEKS AT 12MG/KG FOR PATIENTS LESS THAN 30KG AND 8MG/KG FOR PATIENTS GREATER THAN 30KG. COVERED FOR THE DIAGNOSIS OF GIANT CELL ARTERITIS. COVERED FOR USE WITH A CHIMERIC ANTIGEN RECEPTOR (CAR) T CELL THERAPY FOR POTENTIAL SEVERE OR LIFE-THREATENING CYTOKINE RELEASE SYNDROME. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ACTHAR

## Products Affected

- Acthar H.P.

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR ALL FDA-APPROVED INDICATIONS IN ADULTS, DOCUMENTATION OF SIGNIFICANT SIDE EFFECTS FROM ORAL OR INJECTABLE CORTICOSTEROIDS IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ACTIMMUNE

## Products Affected

- Actimmune

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ADEMPAS

## Products Affected

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | FOR THE DIAGNOSIS OF PULMONARY HYPERTENSION, PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (RIGHT HEART CATHETERIZATION WHICH SHOWS MEAN PULMONARY ARTERY PRESSURE (PAP) OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST. FOR THE DIAGNOSIS OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH), THERE MUST BE DOCUMENTATION OF RECURRENT OR PERSISTENT DISEASE AFTER SURGICAL TREATMENT OR DOCUMENTATION OF INOPERABLE DISEASE (RIGHT HEART CATH IS NOT REQUIRED FOR THE DIAGNOSIS OF CTEPH). |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION WHEN THE PATIENT HAS HAD A RIGHT HEART CATHETERIZATION WITH RESULTS AS LISTED IN THE REQUIRED MEDICAL INFORMATION SECTION. THERE MUST ALSO BE DOCUMENTATON OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GENERIC SILDENAFIL OR ADCIRCA AND ONE OTHER AGENT WITH A DIFFERENT MECHANISM OF ACTION, SUCH AS A PROSTACYCLIN OR AN ENDOTHELIN RECEPTOR ANTAGONIST. COVERED FOR THE TREATMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) |

| PA Criteria | Criteria Details |
| --- | --- |
| | WHEN THE PATIENT HAS DOCUMENTATION OF RECURRENT OR PERSISTANT DISEASE AFTER SURGICAL TREATMENT OR DOCUMENTATION OF INOPERABLE DISEASE. |

# ALPHA-1 ANTITRYPSIN THERAPY

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS AAT SERUM LEVELS, GENOTYPE TESTING, AND PULMONARY FUNCTION TESTING, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST |
| **Coverage Duration** | ONE YEAR, ONLY AS WEEKLY INFUSIONS |
| **Other Criteria** | COVERAGE WILL NOT PROVIDED FOR ALPHA ANTITRYPSIN DEFICIES OTHER THAN THE ONES DEFINED HERE: PATIENTS WITH ALPHA 1 ANTITRYPSIN (AAT) LEVELS BELOW 11MMOL/L (80MG/DL OR APPROXIMATELY 57MG/DL BY NEPHELOMETRY) WHO ARE PIZZ, PISZ, PIZ(NULL), PI(NULL)(NULL), OR HAVE DYSFUNCTIONAL AAT PROTEIN (SUCH AS PIF OR PI PITTSBURG GENOTYPES) AND HAVE EVIDENCE OF EMPHYSEMA AS FEV1 LESS THAN 80% OF PREDICTED VALUE. ADDITIONALLY, PATIENT MUST ALSO DEMONSTRATE 1 OR MORE OF THE FOLLOWING: SIGNS OF SIGNIFICANT LUNG DISEASE SUCH AS CHRONIC PRODUCTIVE COUGH OR UNUSUAL FREQUENCY OF LOWER RESPIRATORY INFECTION, AIRFLOW OBSTRUCTION, ACCELERATED DECLINE OF FEV1 OR CHEST RADIOGRAPH OR CT SCAN EVIDENCE OF EMPHYSEMA, ESPECIALLY IN THE ABSENCE OF A RECOGNIZED RISK FACTOR (SMOKING, OCCUPATIONAL DUST EXPOSURE, ETC) AND PATIENTS WITH |

| PA Criteria | Criteria Details |
| --- | --- |
| | EMPHYSEMA DUE TO AAT DEFICIENCY MUST BE MAINTAINED ON REGIMENS SIMILAR TO THOSE PATIENTS WITH EMPHYSEMA NOT ASSOCIATED WITH AAT DEFICIENCY, INCLUDING: MAXIMUM DOSES OF BETA-ADRENERGIC BRONCHODILATORS, ANTICHOLINERGICS AND ANTIBIOTICS, WHEN APPROPRIATE. PATIENTS MUST ALSO HAVE VACCINATIONS AGAINST INFLUENZA AND PNEUMOCOCCUS AND SUPPLEMENTAL OXYGEN THERAPY WHEN INDICATED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# AMPHETAMINE

## Products Affected

- amphetamine sulfate

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED WHEN USED FOR WEIGHT LOSS, EVEN IF NON-COSMETIC (SUCH AS MORBID OBESITY) |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED WHEN USED FOR THE TREATMENT OF PATIENTS WITH NON-REFRACTORY MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE OR WHEN BEING USED AS A SINGLE AGENT. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES, PERTINENT LAB/DIAGNOSTIC TEST RESULTS. FOR THE DIAGNOSIS OF REFRACTORY MYCOBACTERIUM AVIUM COMPLEX DISEASE, SPUTUM CULTURE RESULTS ARE REQUIRED. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN INFECTIOUS DISEASE SPECIALIST OR PULMONOLOGIST |
| **Coverage Duration** | INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER |
| **Other Criteria** | COVERED FOR PATIENTS WITH REFRACTORY MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE WHO HAVE DOCUMENTATION OF A POSITIVE SPUTUM CULTURE, OBTAINED AFTER A MINIMUM 6 MONTH TREATMENT WITH A MULTI-DRUG REGIMEN (SUCH AS CLARITHROMYCIN/AZITHROMYCIN, RIFAMPIN, AND ETHAMBUTOL). FOR APPROVAL, PATIENT MUST BE USING ARIKAYCE IN COMBINATION WITH OTHER MEDICATIONS AS PART OF A MULTI-DRUG REGIMEN. RECERTIFICATION WILL REQUIRE DOCUMENTATION OF A NEGATIVE SPUTUM CULTURE WHILE TAKING ARIKAYCE TAKEN WITHIN 30 DAYS PRIOR TO THE REQUEST. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# AURYXIA

## Products Affected

- Auryxia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR A DIAGNOSIS OF IRON DEFICIENCY ANEMIA, AS IRON PRODUCTS ARE EXCLUDED FROM PART D COVERAGE. |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | AURYXIA WILL BE COVERED FOR THE CONTROL OF SERUM PHOSPHORUS LEVELS FOR PATIENTS WITH CHRONIC KIDNEY DISEASE ON DIALYSIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# AUSTEDO

## Products Affected

- Austedo oral tablet 12 mg, 6 mg, 9 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | WILL NOT BE COVERED IN COMBINATION WITH TETRABENAZINE (XENAZINE) |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST OR A PSYCHIATRIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# BENLYSTA

## Products Affected

- Benlysta subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR PATIENTS WHO ARE CURRENTLY RECEIVING TREATMENT WITH ANY B-CELL-TARGETED THERAPY OR BIOLOGIC. EXCLUDED FOR PATIENTS WHO HAVE RECEIVED IV CYCLOPHOSPHAMIDE WITHIN THE PAST 180 DAYS. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, DOCUMENTATION THAT PATIENT IS SEROPOSITIVE (ANA EQUAL TO 1:80 AND/OR ANTI-DSDNA EQUAL TO 30 IU PER ML). DUE TO LAB VARIABILITY IN STANDARDS FOR POSITIVE VALUES, CONSIDERATION WILL BE GIVEN IF THE REPORTED LAB RESULTS DO NOT MEET THE VALUES LISTED ABOVE, BUT ARE REPORTED AS POSITIVE FROM THAT LAB. |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE FOLLOWED BY A RHEUMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE TREATMENT OF ADULT PATIENTS WITH ACTIVE, AUTOANTIBODY-POSITIVE, SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) WHO ARE RECEIVING STANDARD THERAPY. THE PATIENT MUST BE TAKING AT LEAST ONE AGENT USED TO MANAGE SLE, SUCH AS CORTICOSTEROIDS, IMMUNOSUPPRESSANTS, OR ANTIMALARIALS. REQUESTS WILL ALSO BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# BERINERT

## Products Affected

- Berinert intravenous kit

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR THE PROPHYLAXIS OF HEREDITARY ANGIOEDEMA ATTACKS. |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND LABORATORY TESTS USED TO CONFIRM DIAGNOSIS, AND DOCUMENTATION OF ANY PREVIOUS THERAPIES. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III FOR THE TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACKS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# CARBAGLU

## Products Affected

- Carbaglu

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | PATIENT MUST HAVE A DIAGNOSIS OF ACUTE OR CHRONIC HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS). |

# CERDELGA

## Products Affected

- Cerdelga

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | COMBINATION THERAPY WITH CERDELGA AND ENZYME REPLACEMENT THERAPY (SUCH AS ELEYSO, CEREZYME) IS EXCLUDED. CONCOMITANT USE OF A MODERATE OR STRONG CYP2D6 INHIBITOR WITH A MODERATE OR STRONG CYP3A INHIBITOR IN EXTENSIVE METABOLIZERS OR INTERMEDIATE METABOLIZERS IS EXCLUDED. CONCOMITANT USE OF A STRONG CYP3A INHIBITOR IN POOR METABOLIZERS OR INTERMEDIATE METABOLIZERS IS EXCLUDED. CERDELGA IS EXCLUDED IN PATIENTS WITH PRE-EXISTING CARDIAC DISEASE, LONG Q-T SYNDROME, AND FOR THOSE WHO TAKE CLASS 1A OR CLASS III ANTIARRHYTHMIC. |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS ENZYME ANALYSIS, MUTATION ANALYSIS, OR BONE MARROW STUDIES, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | CERDELGA IS COVERED FOR TYPE 1 GAUCHER DISEASE IN PATIENTS WHO ARE CYP2D6 EXTENSIVE METABOLIZERS, INTERMEDIATE METABOLIZERS OR POOR METABOLIZERS. |

# CESAMET

## Products Affected

- Cesamet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | 6 MONTHS |
| **Other Criteria** | COVERED FOR THE PROPHYLAXIS OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY WITH DOCUMENTED LACK OF RESPONSE OR SEVERE INTOLERANCE TO ONE 5HT-3 RECEPTOR ANTAGONIST. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# CGRP ANTAGONISTS

## Products Affected

- Aimovig Autoinjector (2 Pack)
- Ajovy
- Emgality Pen
- Emgality Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF EPISODIC OR CHRONIC MIGRAINE HEADACHE. PATIENT MUST BE EXPERIENCING 4 OR MORE MIGRAINE HEADACHE DAYS PER MONTH. PATIENT MUST HAVE BEEN TREATED WITH TWO DIFFERENT CLASSES OF MEDICATIONS FOR A THREE-MONTH PERIOD THAT ARE SUPPORTED BY COMPENDIA FOR THE PROPHYLACTIC TREATMENT OF MIGRAINE HEADACHE (SUCH AS SPECIFIC ANTICONVULSANTS, ANTIDEPRESSANTS, OR BETA-BLOCKERS), WHICH RESULTED IN INTOLERANCE OR LACK OF CLINICAL EFFICACY. FOR CLINICAL FAILURE DUE TO INTOLERANCE, A THREE-MONTH TRIAL OF MEDICATION IS NOT REQUIRED. UPON RECERTIFICAITON, PRESCRIBER MUST ATTEST TO THE CLINICAL RESPONSE TO TREATMENT, DEFINED AS A REDUCTION IN THE NUMBER OF MIGRAINE HEADACHE DAYS PER MONTH COMPARED TO PRE-TREATMENT. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# CHOLBAM

## Products Affected

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS GAS CHROMATOGRAPHY-MASS SPECTROMETRY URINE ANALYSIS, LIVER FUNCTION TESTS AND OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS). |
| **Age Restrictions** | PATIENT MUST BE 3 WEEKS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST, GASTROENTEROLOGIST, GENETICIST, HEPATOLOGIST, OR METABOLIC SPECIALIST. |
| **Coverage Duration** | INITIAL APPROVAL 3 MONTHS. ONE YEAR FOR SUBSEQUENT REVIEWS |
| **Other Criteria** | FOR ITS FDA-APPROVED INDICATIONS, THERE MUST BE A DIAGNOSIS MADE BY GAS CHROMATOGRAPHY-MASS SPECTROMETRY ANALYSIS OF THE URINE WITH A POSITIVE IDENTIFICATION OF ELEVATED BILE ACIDS. IN ADDITION, LIVER FUNCTION TESTS MUST IDENTIFY ELEVATED SERUM AMINOTRANSFERASES WITH NORMAL SERUM GAMMA GLUTAMYLTRANSFERASE. THE INITIAL APPROVAL WILL BE FOR THREE MONTHS. AFTER THE INITIAL THREE MONTH AUTHORIZATION, APPROVAL WILL BE GRANTED IN ONE YEAR INCREMENTS WITH DOCUMENTATION OF IMPROVED LIVER FUNCTION VIA AMINOTRANSFERASE LOWERING. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# CIALIS FOR DAILY USE

## Products Affected

- Cialis oral tablet 2.5 mg, 5 mg
- tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | CIALIS FOR DAILY USE WILL NOT BE COVERED FOR THE INDEPENDENT DIAGNOSIS OF ERECTILE DYSFUNCTION. CIALIS IS EXCLUDED FOR OFF-LABEL INDICATIONS EVEN IF SUPPORTED BY AHFS OR DRUGDEX COMPENDIUM. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH). |

# CIMZIA

## Products Affected

- Cimzia
- Cimzia Powder for Reconst

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST FOR CROHN'S DISEASE DIAGNOSIS. RHEUMATOLOGIST FOR RHEUMATOID ARTHRITIS OR ANKYLOSING SPONDYLOSIS DIAGNOSES. RHEUMATOLOGIST OR DERMATOLOGIST FOR PSORIATIC ARTHRITIS DIAGNOSIS |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | CIMZIA WILL BE COVERED FOR A DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE IN PATIENTS WITH A DOCUMENTED FAILURE OF BOTH HUMIRA AND STELARA. CIMZIA WILL BE COVERED FOR A DIAGNOSIS OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR. CIMZIA WILL BE COVERED FOR A DIAGNOSIS OF ANKYLOSING SPONDYLITIS IN PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA. CIMZIA WILL BE COVERED FOR A DIAGNOSIS OF PSORIATIC ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE OF TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, ORENCIA, STELARA, XELJANZ/XELJANZ XR. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE |

| PA Criteria | Criteria Details |
| --- | --- |
| | AREA (BSA). COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. IN ADDITION, THERE MUST BE DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# CINRYZE

## Products Affected

- Cinryze

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR ACUTE HEREDITARYANGIOEDEMA ATTACKS |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND LABORATORY TESTS USED TO CONFIRM DIAGNOSIS, AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III. PROPHYLACTIC THERAPY WITH CINRYZE WILL BE COVERED IN INDIVIDUALS WITH AT LEAST ONE SEVERE EPISODE OF ANGIOEDEMA PER MONTH. IN ADDITION, THE PATIENT MUST HAVE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF STEROIDS OR DANAZOL. |

# COPAXONE 20MG

## Products Affected

- Copaxone subcutaneous syringe 20 mg/mL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MULTIPLE SCLEROSIS. DOCUMENTATION OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GLATOPA OR GLATIRAMER IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# COSENTYX

## Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A DERMATOLOGIST OR RHEUMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS WITH PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE AREA (BSA). COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS IN PATIENTS WITH PSORIASIS THAT INVOLVES LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. PATIENTS ALSO MUST MEET ONE OF THE FOLLOWING CRITERIA: 1) HAD A 3-MONTH TRIAL OF ACITRETIN, METHOTREXATE, OR CYCLOSPORINE THERAPY RESULTING IN INTOLERANCE OR CLINICAL FAILURE OR 2) HAVE TRIED UVB/COAL TAR OR PUVA/TOPICALCORTICOSTEROIDS FOR AT LEAST 3 MONTHS OR 3) HAVE TRIED AND FAILED AT LEAST TWO OF THE FOLLOWING FOR 3 MONTHS: TREATMENT WITH MEDIUM AND/OR HIGH POTENCY TOPICAL CORTICOSTEROIDS OR ANTHRALIN, CALCIPOTRIENE, OR TAZAROTENE. COVERED FOR THE DIAGNOSIS OF ANKYLOSING SPONDYLITIS IN PATIENTS WITH REFRACTORY DISEASE DEFINED BY FAILURE OF AT LEAST ONE NSAID TAKEN FOR A MINIMUM ONE-MONTH DURATION. COVERED FOR A DIAGNOSIS OF PSORIATIC |

| PA Criteria | Criteria Details |
| --- | --- |
| | ARTHRITIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# DAKLINZA

## Products Affected

- Daklinza

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | DAKLINZA WILL NOT BE COVERED IN COMBINATION WITH DRUGS THAT STRONGLY INDUCE CYP3A. DAKLINZA WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF HARVONI OR MAVYRET OR EPCLUSA TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO HARVONI OR MAVYRET OR EPCLUSA. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# DICLOFENAC 3% TOPICAL GEL

## Products Affected

- diclofenac sodium topical gel 3 %

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | DICLOFENAC 3% GEL WILL BE COVERED FOR THE DIAGNOSIS OF ACTINIC KERATOSES. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# DOPTELET

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A HEMATOLOGIST, GASTROENTEROLOGIST, OR HEPATOLOGIST |
| **Coverage Duration** | ONE MONTH |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF THROMBOCYTOPENIA DEFINED AS A PLATELET COUNT OF LESS THAN 50000 PLATELETS PER MICROLITER. IN ADDITION, THE PATIENT MUST HAVE A DIAGNOSIS OF CHRONIC LIVER DISEASE AND BE SCHEDULED TO UNDERGO A PROCEDURE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# DOXEPIN TOPICAL CREAM

## Products Affected

- doxepin topical

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | DOXEPIN TOPICAL CREAM WILL BE COVERED FOR THE TREATMENT OF SHORT-TERM MANAGEMENT OF MODERATE PRURITUS IN ADULTS WITH ATOPIC DERMATITIS OR LICHEN SIMPLEX CHRONICUS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# DUPIXENT

## Products Affected

- Dupixent subcutaneous syringe 200 mg/1.14 mL, 300 mg/2 mL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS IN PATIENTS AT LEAST 18 YEARS OLD WITH ATOPIC DERMATITIS THAT INVOLVES AT LEAST 10% BODY SURFACE AREA (BSA). IN ADDITION, THE PATIENT MUST HAVE RECEIVED TREATMENT WITH TWO OF THE FOLLOWING THREE TREATMENT OPTIONS DURING THE SIX MONTHS PRECEEDING THE REQUEST FOR DUXIPENT. 1) TREATMENT WITH A POTENT TOPICAL CORTICOSTEROID FOR A MINIMUM 14-DAY DURATION OR TREATMENT WITH A MEDIUM POTENCY TOPICAL CORTICOSTEROID FOR A MINIMUM 28-DAY DURATION. 2) TREATMENT WITH TOPICAL TACROLIMUS. 3) TREATMENT WITH AN ORAL OR INJECTABLE IMMUNOSUPPRESSANT, SUCH AS A CORTICOSTEROID, INDICATED OR COMPENDIA-SUPPORTED FOR THE TREATMENT OF ATOPIC DERMATITIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# DUZALLO

## Products Affected

- Duzallo oral tablet 200-300 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, CURRENT SERUM URIC ACID LEVEL |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | DUZALLO IS COVERED FOR A DIAGNOSIS OF GOUT IN PATIENTS WITH SERUM URIC ACID LEVELS ABOVE 6.5MG/DL DESPITE CURRENT THERAPY WITH ALLOPURINOL (300MG DAILY OR 200MG DAILY IF RENAL IMPAIRMENT) OR FEBUXOSTAT (80MG DAILY). IN ADDITION, THE PATIENT MUST HAVE SIGNIFICANT INTOLERANCE, THERAPEUTIC FAILURE, OR CONTRAINDICATION (SUCH AS A SULFA ALLERGY) TO PROBENECID. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# EGRIFTA

## Products Affected

- Egrifta subcutaneous recon soln 1 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT MEDICATIONS (REQUIRED THAT PATIENT BE CURRENTLY ON ANTIRETROVIRAL THERAPY). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# EMFLAZA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, RESULTS OF DUCHENNE MUSCULAR DYSTROPHY (DMD) GENE MUTATION STUDY |
| **Age Restrictions** | PATIENT MUST BE 5 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR ALL FDA-APPROVED INDICATIONS WITH REQUIRED DOCUMENTATION OF SIGNIFICANT SIDE EFFECTS RESULTING FROM A MINIMUM 3-MONTH TRIAL OF ORAL PREDNISONE. EXAMPLES OF SIGNIFICANT PREDNISONE SIDE EFFECTS INCLUDE CUSHINGOID APPEARANCE, CENTRAL (TRUNCAL) OBESITY, UNDESIRABLE WEIGHT GAIN, INABILITY TO MANAGE DIABETES OR HYPERTENSION, STEROID-INDUCED MANIA, OR SEPSIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ENBREL

## Products Affected

- Enbrel subcutaneous recon soln
- Enbrel subcutaneous syringe
- Enbrel SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | PATIENT MUST NOT HAVE A CONTRAINDICATION TO TNF THERAPY |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | FOR TREATMENT OF PSORIASIS, PATIENTS MUST BE 4 YEARS OF AGE OR OLDER. FOR THE TREATMENT OF ARTHRITIS, THE PATIENT MUST BE AT LEAST 2 YEARS OLD. |
| **Prescriber Restrictions** | PRESCRIBER MUST BE A RHEUMATOLOGIST (FOR A DIAGNOSIS OF PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, RHEUMATOID ARTHRITIS, OR JUVENILE IDIOPATHIC ARTHRITIS) OR DERMATOLOGIST (FOR A DIAGNOSIS OF PSORIASIS). |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ENBREL IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS. PSORIASIS- IN ADULT PTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE AREA. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS IN PATIENTS WITH LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. PATIENT ALSO MUST MEET ONE OF THE FOLLOWING CRITERIA (REQMT BYPASSED IF PT HAS TRIED UVB AND COAL TAR OR PUVA AND TOPICAL CORTICOSTEROIDS--A NON-PART-D SERVICE): 1) HAD A 3 MONTH TRIAL OF ACITRETIN, METHOTREXATE, OR CYCLOSPORINE THERAPY RESULTING IN INTOLERANCE OR CLINICAL FAILURE OR 2) HAVE TRIED AND FAILED AT LEAST 2 OF THE FOLLOWING FOR 3 MONTHS: TREATMENT WITH |

| PA Criteria | Criteria Details |
| --- | --- |
| | MEDIUM AND/OR HIGH POTENCY TOPICAL CORTICOSTEROIDS OR ANTHRALIN, CALCIPOTRIENE, OR TAZAROTENE. ANKYLOSING SPONDYLITIS- IN PTS WITH REFRACTORY DISEASE DEFINED BY FAILURE OF AT LEAST TWO NSAIDS FOR AT LEAST 1 MONTH EACH. RHEUMATOID ARTHRITIS- IN PTS WITH ACTIVE MODERATE TO SEVERE RA WHO HAVE FAILED TO RESPOND TO AND/OR IS INTOLERANT TO ONE APPROVED DISEASE-MODIFYING ANTI-RHEUMATIC DRUG (DMARD) AGENTS, SUCH AS METHOTREXATE, AZATHIOPRINE, SULFASALAZINE, OR HYDROXYCHLOROQUINE, EITHER ALONE OR IN COMBINATION FOR A 3 MONTH PERIOD. COVERED FOR THE DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE JUVENILE IDIOPATHIC ARTHRITIS IN PATIENTS AT LEAST 2 YEARS OLD. THE PATIENT MUST HAVE FAILED TO RESPOND TO AND/OR IS INTOLERANT TO APPROVED DMARD AGENTS, SUCH AS METHOTREXATE, NSAIDS, ANALGESICS OR CORTICOSTEROIDS, EITHER ALONE OR IN COMBINATION. REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# ENDARI

## Products Affected

- Endari

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 5 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A HEMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR SYMPTOMATIC PAIN RELIEF OF SICKLE CELL DISEASE. IN ADDITION, PATIENT MUST HAVE EXPERIENCED INADEQUATE PAIN RELIEF WITH A MINIMUM THREE-MONTH TRIAL OR A HEMATOLOGIC TOXICITY REACTION WITH HYDROXYUREA MONO-THERAPY. HEMATOLOGIC TOXICITY WITH HYDROXYUREA IS DEFINED BY NEUTROPHIL, PLATELET, HEMOGLOBIN AND/OR RETICULOCYTE COUNT ABNORMALITIES CONCURRENT WITH HYDROXYUREA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# EPCLUSA

## Products Affected

- Epclusa
- sofosbuvir-velpatasvir

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EPCLUSA WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA-APPROVED INDICATION, COMPENDIA, OR AASLD/IDSA GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO INCLUDE BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# EPIDIOLEX

## Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ESBRIET

## Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ESBRIET WILL BE COVERED FOR A DOCUMENTED DIAGNOSIS OF IDIOPATHIC PULMONARY FIBROSIS. |

# ESRD

## Products Affected

- Aranesp (in polysorbate) injection solution 100 mcg/mL, 200 mcg/mL, 25 mcg/mL, 300 mcg/mL, 40 mcg/mL, 60 mcg/mL
- Aranesp (in polysorbate) injection syringe
- Epogen injection solution 2,000 unit/mL, 20,000 unit/2 mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL
- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, DIALYSIS STATUS (ONLY IF DIAGNOSIS OF END-STATE RENAL DISEASE) |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR A DIAGNOSIS OF END STAGE RENAL DISEASE ON DIALYSIS, CMS EXPECTS THAT THIS DRUG SHOULD ROUTINELY BE PROVIDED BY A DIALYSIS CENTER AND BILLED TO MEDICARE PART B AS PART OF A BUNDLED PAYMENT ARRANGEMENT (IF APPLICABLE). ALL OTHER DIAGNOSES UNRELATED TO END STAGE RENAL DISEASE ON DIALYSIS WOULD BE EVALUATED FOR COVERAGE UNDER THE PART D BENEFIT. |

# FANAPT/LATUDA/SAPHRIS

## Products Affected

- Fanapt
- Latuda
- Saphris

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERAGE OF LATUDA FOR A DIAGNOSIS OF BIPOLAR DEPRESSION REQUIRES DOCUMENTATION OF SIGNIFICANT INTOLERANCE OR THERAPEUTIC FAILURE OF ONE FIRST LINE TREATMENT (SUCH AS LITHIUM, VALPROATE, LAMOTRIGINE, OLANZAPINE, QUETIAPINE). COVERAGE OF SAPHRIS, LATUDA, OR FANAPT FOR THE DIAGNOSIS OF SCHIZOPHRENIA OR SAPHRIS FOR THE DIAGNOSIS OF BIPOLAR DISORDER REQUIRES DOCUMENTATION OF SIGNIFICANT INTOLERANCE OR THERAPEUTIC FAILURE OF ONE FIRST LINE TREATMENT (SUCH AS RISPERIDONE, OLANZAPINE, ZIPRASIDONE, QUETIAPINE). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# FASENRA

## Products Affected

- Fasenra

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | ADMINISTRATION BY ANYONE OTHER THAN A HEALTHCARE PROFESSIONAL IS EXCLUDED. FASENRA WILL NOT BE COVERED FOR THE TREATMENT OF OTHER EOSINOPHILIC CONDITIONS OR FOR RELIEF OF ACUTE BRONCHOSPASM OR STATUS ASTHMATICUS. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM THE DIAGNOSIS OF EOSINOPHILIC ASTHMA (SUCH AS BLOOD EOSINOPHIL COUNT, PULMONARY FUNCTION TESTS, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ALLERGIST/IMMUNOLOGIST OR PULMONOLOGIST |
| **Coverage Duration** | INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YEAR THEREAFTER |
| **Other Criteria** | FASENRA IS COVERED FOR THE TREATMENT OF SEVERE PERSISTENT ASTHMA WITH AN EOSINOPHILIC PHENOTYPE. FOR A PATIENT NOT DEPENDENT ON ORAL STEROIDS, THE PATIENT MUST HAVE A PERIPHERAL BLOOD EOSINOPHIL COUNT OF AT LEAST 300 CELLS PER MICROLITER WITHIN THE PRECEDING 6 WEEKS BEFORE THE FASENRA REQUEST. FOR A PATIENT DEPENDENT ON ORAL STEROIDS, THE PATIENT MUST HAVE A PERIPHERAL BLOOD EOSINOPHIL COUNT OF AT LEAST 150 CELLS PER MICROLITER WITHIN THE PRECEDING 6 WEEKS BEFORE FASENRA REQUEST. FOR ADULTS, PATIENT MUST HAVE A PRE-BRONCHODILATOR FORCED EXPIRATORY VOLUME IN 1 SECOND (FEV1) OF LESS THAN 80 PERCENT OF THE PREDICTED VALUE. FOR PATIENTS AGES 12-18 YEARS, PATIENT MUST HAVE A PRE-BRONCHODILATOR FEV1 OF LESS |

| PA Criteria | Criteria Details |
| --- | --- |
| | THAN 90% OF THE PREDICTED VALUE OR A RATIO OF THE FEV1 TO THE FORCED VITAL CAPACITY (FVC) OF LESS THAN 0.8. THE PATIENT MUST BE MAINTAINED ON ASTHMA TREATMENT CONSISTENT WITH THE NHLBI GUIDELINES, WHICH RECOMMEND THE COMBINATION OF A HIGH DOSE INHALED STEROID WITH ONE OTHER CONTROLLER MEDICATION, SUCH AS A LONG-ACTING BETA AGONIST, LEUKOTRIENE INHIBITOR, OR THEOPHYLLINE. IF THE ABOVE CRITERIA IS MET, COVERAGE WILL BE PROVIDED IF THE PATIENT EXPERIENCED 1 OR MORE ASTHMA EXACERBATIONS (DEFINED AS UNSCHEDULED DOCTOR VISITS, URGENT CARE VISITS, EMERGENCY ROOM VISITS, HOSPITAL ADMISSIONS, OR DOCUMENTED NEED FOR ACUTE SYSTEMIC STEROIDS) WITHIN THE PRECEDING 12 MONTHS. INITIAL APPROVAL WILL BE FOR 6 MONTHS. UPON RECERTIFICATION, DOCUMENTATION SHOULD BE PROVIDED VALIDATING REDUCTION IN ASTHMA EXACERBATIONS AS DEFINED ABOVE. REQUESTS WILL ALSO BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# FIRAZYR

## Products Affected

- Firazyr

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR PROPHYLAXIS OF HEREDITARYANGIOEDEMA ATTACKS |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (NO SPECIFIC TESTS ARE REQUIRED, BUT IF TESTS WERE PERFORMED TO CONFIRM THE DIAGNOSIS, PROVIDING THE RESULTS WILL REDUCE THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | EXCLUDED IN PATIENTS UNDER 18 YEARS OF AGE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ACUTE THERAPY WITH FIRAZYR WILL BE COVERED IN INDIVIDUALS WITH A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# FIRDAPSE

## Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST OR NEUROMUSCULAR SPECIALIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR PATIENTS WITH A DIAGNOSIS OF LAMBERT-EATON MYASTHENIC SYNDROME THAT HAS BEEN CONFIRMED BY ELECTROMYOGRAPHY OR CALCIUM CHANNEL ANTIBODY TESTING. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# FLECTOR

## Products Affected

- Flector

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | THREE MONTHS |
| **Other Criteria** | FLECTOR WILL BE COVERED FOR THE TREATMENT OF ACUTE PAIN DUE TO MINOR STRAINS, SPRAINS, AND CONTUSIONS. ACUTE PAIN IS DEFINED AS SHORT-TERM PAIN NOT LASTING LONGER THAN A THREE MONTH PERIOD. CHRONIC PAIN IS DEFINED AS A CONDITION THAT REQUIRES PAIN MANAGEMENT THAT EXCEEDS A THREE MONTH PERIOD, SUCH AS RHEUMATOID ARTHRITIS, OSTEOARTHRITIS AND PERIPHERAL NEUROPATHY. |

# GALAFOLD

## Products Affected

- Galafold

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED IN COMBINATION WITH FABRAZYME (AGALSIDASE BETA). EXCLUDED FOR PATIENTS WITH A GLOMERULAR FILTRATION RATE (GFR) LESS THAN OR EQUAL TO 30 ML/MIN. |
| **Required Medical Information** | IN MALE PATIENTS, DIAGNOSIS CONFIRMED BY EITHER AN ENZYME ASSAY TEST (IN LEUKOCYTES, PLASMA, FIBROBLASTS OR DRIED BLOOD SPOTS) DEMONSTRATING COMPLETE DEFICIENCY OR LESS THAN 3% OF NORMAL OF ALPHA-GLACTOSIDASE A (GLA) ACTIVITY, OR DOCUMENTED GLA GENE MUTATION BY GENE SEQUENCING. FOR FEMALE PATIENTS, DOCUMENTATION MUST BE CONFIRMED BY DOCUMENTED GLA MUTATION BY GENE MUTATION. INDICATE CURRENT THERAPIES FOR THE TREATMENT OF FABRY DISEASE. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GENETIC SPECIALIST OR PRESCRIBER EXPERIENCED IN THE MANAGEMENT OF FABRY DISEASE |
| **Coverage Duration** | ONE YEAR FOR INITIAL APPROVAL. TWO YEARS FOR RECERTIFICATION |
| **Other Criteria** | COVERED FOR A CONFIRMED DIAGNOSIS OF FABRY DISEASE. IN ADDITION, MALE AND FEMALE PATIENTS MUST HAVE AN AMENABLE GENE MUTATION BASED ON THE HUMAN EMBRYONIC KIDNEY (HEK) 293 ASSAY (REFER TO MANUFACTURER PRESCRIBING INFORMATION FOR THE LISTING OF AMENABLE GLA VARIANTS). THE PATIENT MUST ALSO HAVE AT LEAST ONE OF THE FOLLOWING DOCUMENTED SYMPTOMS OR PHYSICAL FINDINGS OF FABRY DISEASE: ANGIOKERATOMAS (CHARACTERISTIC LYSOSOMAL DISEASE SKIN RASHES), HYPOHIDROSIS (DECREASED SWEATING), |

| PA Criteria | Criteria Details |
| --- | --- |
| | ACROPARESTHESIA (NEUROPATHIC PAIN IN THE HANDS AND FEET), CORNEA VERTICILLATA AND CHARACTERISTIC CORNEAL /LENTICULAR OPACITIES, DIARRHEA, ABDOMINAL PAIN, NAUSEA, VOMITING, FLANK PAIN, HEAT/COLD INTOLERANCE, VERTIGO, TINNITUS, DIPLOPIA, FATIGUE , CARDIAC DISEASE (INCLUDING HYPERTROPHIC CARDIOMYOPATHY), ARRHYTHMIAS, PROGRESSING RENAL DISEASE (PROTEINURIA TO END STAGE RENAL DISEASE), AND STROKE. MALE PATIENTS WITH COMPLETE DEFICIENCY OR LESS THAN 3% OF NORMAL ALPHA-GALACTOSIDASE A ACTIVITY ARE NOT REQUIRED TO HAVE ONE OF THE SYMPTOMS OR PHYSICAL FINDINGS ABOVE. REQUESTS FOR RECERTIFICATION WILL REQUIRE DOCUMENTATION THAT SUPPORTS A POSITIVE RESPONSE TO THERAPY FOR SYMPTOMATIC INDIVIDUALS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# GATTEX

## Products Affected

- Gattex 30-Vial

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS (AND DEPENDENCY ON PARENTERAL NUTRITION SUPPORT), PERTINENT LAB/DIAGNOSTIC TEST RESULTS (NO SPECIFIC TESTS ARE REQUIRED, BUT IF TESTS WERE PERFORMED TO CONFIRM THE DIAGNOSIS, PROVIDING THE RESULTS WILL REDUCE THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | SIX MONTHS |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# GOCOVRI

## Products Affected

- Gocovri oral capsule,extended release 24hr 137 mg, 68.5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED IN COMBINATION WITH A LEVODOPA-BASED THERAPY FOR THE TREATMENT OF DYSKINESIA ASSOCIATED WITH PARKINSON'S DISEASE. IN ADDITION, THE PATIENT MUST HAVE SIGNIFICANT INTOLERANCE, THERAPEUTIC FAILURE, OR CONTRAINDICATION TO IMMEDIATE-RELEASE AMANTADINE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# GONADOTROPIN RELEASING HORMONE ANALOGS

## Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Trelstar intramuscular suspension for reconstitution

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | FOR LUPRON, AND LUPRON DEPOT, PATIENT MUST BE 2 YEARS OF AGE OR OLDER. FOR ELIGARD AND TRELSTAR, PATIENT MUST BE 18 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | 6 MONTHS FOR ENDOMETRIOSIS. ONE YEAR FOR ALL OTHER DIAGNOSES. |
| **Other Criteria** | LUPRON/LEUPROLIDE IS COVERED FOR MANAGEMENT OF ENDOMETRIOSIS, INCLUDING PAIN RELIEF AND REDUCTION OF ENDOMETRIOTIC LESIONS. AUTHORIZATION WILL BE FOR UP TO 6 MONTHS, BECAUSE OF A LACK OF SAFETY DATA WITH LONG TERM USE, AND CONCERNS REGARDING EFFECTS ON BONE DENSITY. LUPRON/LEUPROLIDE IS COVERED FOR TREATMENT OF ADVANCED PROSTATIC CANCER, DEFINED AS STAGE III OR STAGE IV. LUPRON/LEUPROLIDE IS COVERED FOR TREATMENT OF PRECOCIOUS PUBERTY. LUPRON/LEUPROLIDE IS COVERED AS ADJUNCT THERAPY FOR PREOPERATIVE HEMATOLOGIC IMPROVEMENTS OF PATIENTS WITH ANEMIA (HEMATOCRIT LESS THAN OR EQUAL TO 30% AND OR |

| PA Criteria | Criteria Details |
| --- | --- |
| | HEMOGLOBIN LESS THAN OR EQUAL TO 10.2 G/DL) CAUSED BY UTERINE LEIOMYOMATA.TRELSTAR IS COVERED FOR PALLIATIVE TREATMENT OF ADVANCED PROSTATE CANCER. REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# GRALISE

## Products Affected

- Gralise 30-Day Starter Pack
- Gralise oral tablet extended release 24 hr 300 mg, 600 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR THE TREATMENT OF POST-HERPETIC NEURALGIA, THERE MUST BE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE TO GENERIC GABAPENTIN. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABELUSE REQUIREMENTS. |

# GROWTH HORMONE

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | WHEN USED TO INCREASE HEIGHT, GROWTH HORMONE THERAPY WILL NOT BE COVERED IN PEDIATRIC PATIENTS WITH CLOSED EPIPHYSES. |
| **Required Medical Information** | GENERAL-GROWTH CHARTS, HEIGHT/WEIGHT, HEIGHT VELOCITY, PATIENT PROGRESS NOTES. SOMATOTROPIN DEFICIENCY IN CHILDREN REQUIRES DOCUMENTATION OF DIMINISHED GROWTH HORMONE RESPONSE (MAX PEAK LESS THAN 10NG/ML) TO 2 OR MORE DIFFERENT PROVOCATION TESTS (SUCH AS LEVODOPA, INSULIN-INDUCED HYPOGLYCEMIA, ARGININE, CLONIDINE, OR GLUCAGON) OR DOCUMENTATION OF LOW IGF-1 OR IGFBP3 FOR AGE, SEX, AND PUBERTAL STATUS IN CHILDREN AGE 6 OR GREATER IN THE ABSENCE OF CHRONIC DISEASE ALONG WITH A HEIGHT VELOCITY LESS THAN 25TH PERCENTILE IN THE 6-12 MONTHS PRIOR TO GROWTH HORMONE THERAPY. IN ADDITION TO ONE OF THE ABOVE FINDINGS THERE MUST ALSO BE DOCUMENTATION OF TWO OF THE FOLLOWING: 1) GROWTH VELOCITY LESS THAN 7CM/YR BEFORE AGE THREE 2) BONE AGE AT LEAST 2 SD BELOW NORMAL FOR CHRONOLOGICAL AGE 3) A KNOWN RISK FACTOR FOR GROWTH HORMONE DEFICIENCY (SUCH AS CONGENITAL HYPOPITUITARISM, PANHYPOPITUITARISM, OR PRIOR BRAIN RADIATION). SOMATOTROPIN DEFICIENCY IN ADULTS REQUIRES DOCUMENTATION OF NEGATIVE RESPONSE TO PROVOCATIVE TEST WITH MAX PEAK OF 5NG/ML ALONG WITH DOCUMENTATION OF CLINICAL SYMPTOMS SUCH AS INCREASED WEIGHT AND BODY FAT MASS, DECREASED LEAN BODY MASS, DECREASED EXERCISE TOLERANCE, DECREASED |

| PA Criteria | Criteria Details |
|---|---|
| | MUSCLE MASS AND STRENGTH, REDUCED CARDIAC PERFORMANCE, REDUCED BONE DENSITY, POOR SLEEP, IMPAIRED SENSE OF WELL-BEING OR LACK OF MOTIVATION. ALTERNATIVELY, WILL ACCEPT INSULIN TOLERANCE TEST WITH MAX PEAK LESS THAN 5NG/ML (UNLESS CONTRAINDICATED IN WHICH CASE WILL ACCEPT IV ARGININE IN COMBINATION WITH GH-RELEASING HORMONE WITH MAX PEAK LESS THAN 10NG/ML.) IF THERE IS DOCUMENTATION OF DEFICIENCY OF 3 OR MORE PITUITARY HORMONES, ITT OR ARGININE TESTS ARE NOT REQUIRED. RECERTIFICATION- IN CHILDREN REQUIRES THE FOLLOWING EVERY 12 MONTHS: CURRENT GROWTH VELOCITY, GROWTH CHARTS (HEIGHT AND WEIGHT), CURRENT BONE AGE, PUBERTY STATUS, AND RADIOGRAPHIC TESTING TO DETERMINE IF EPIPHYSES ARE CLOSED AT AGE 14 IN GIRLS AND AGE 16 IN BOYS. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST, PEDIATRIC ENDOCRINOLOGIST, NEPHROLOGIST, INFECTIOUS DISEASE SPECIALIST, OR GASTROENTEROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | CHILDREN-COVERED FOR TREATMENT OF SHORT STATURE IN TURNER SYNDROME. COVERED FOR CHILDREN WITH HEIGHT LESS THAN 3RD PERCENTILE FOR CHRONOLOGICAL AGE WITH RENAL INSUFFICIENCY DEFINED AS SERUM CREATININE GREATER THAN 3.0 MG/DL OR CREATININE CLEARANCE OF 5-75 ML/MIN PER 1.73M3 BEFORE RENAL TRANSPLANT. COVERED FOR PRADER-WILLI SYNDROME WITH SHORT STATURE OR GROWTH FAILURE. COVERED FOR CHILDREN WITH INTRAUTERINE GROWTH FAILURE OR SMALL FOR GESTATIONAL AGE WHO DO NOT CATCH UP BY 2 YEARS OF AGE. COVERED FOR NOONAN SYNDROME WITH SHORT STATURE (WHEN HEIGHT IS AT LEAST 2 SD BELOW NORMAL. COVERED FOR CHILDREN WITH SHOX DEFICIENCY DEMONSTRATED BY CHROMOSOME ANALYSIS AND WHOSE EPIPHYSES ARE NOT CLOSED. ADULTS AND CHILDREN-GROWTH HORMONE THERAPY IS COVERED FOR A DIAGNOSIS OF SOMATOTROPIN DEFICIENCY (SEE REQUIRED MEDICAL INFO). COVERED FOR AIDS WASTING OR CACHEXIA OR |

| PA Criteria | Criteria Details |
| --- | --- |
| | CHILDREN WITH HIV ASSOCIATED FAILURE TO THRIVE DEFINED AS A GREATER THAN 10% OF BASELINE WEIGHT LOSS OR WEIGHT LESS THAN 90% OF IDEAL BODY WEIGHT AND EITHER CHRONIC DIARRHEA OR CHRONIC WEAKNESS NOT OTHERWISE EXPLAINED. COVERED FOR PATIENTS WITH SHORT BOWEL SYNDROME WHO ARE EXPERIENCING MALABSORPTION, MALNUTRITION, WEIGHT LOSS OR DEHYDRATION DESPITE SPECIALIZED NUTRITIONAL SUPPORT. NOTE- OMNITROPE MUST BE USED WHEN THE DIAGNOSIS IS GROWTH HORMONE DEFICIENCY, PRADER-WILLI SYNDROME OR SMAL FOR GESTATIONAL AGE EXCEPT IN THE FOLLOWING SITUATIONS: HUMATROPE OR GENOTROPIN WILL BE AUTHORIZED ONLY WHEN THE PATIENT HAS A DOCUMENTED SENSITIVITY TO BOTH BENZYL ALCOHOL (IN OMNITROPE 5 PEN AND VIALS) AND PHENOL (IN OMNITROPE 10 PEN). IF A PATIENT HAS A SENSITIVITY JUST ONE OF THESE AGENTS, THEN THE ALTERNATIVE OMNITROPE PRODUCT MUST BE USED. IF THE PATIENT IS AGE 3 AND UNDER, THEN OMNITROPE 10 PEN SHOULD BE USED AS BENZYL ALCOHOL SHOULD BE AVOIDED IN THIS POPULATION |

# HAEGARDA

## Products Affected

- Haegarda

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR ACUTE HEREDITARY ANGIOEDEMA ATTACKS |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 12 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | PENDING CMS APPROVAL |

# HARVONI

## Products Affected

- Harvoni
- ledipasvir-sofosbuvir

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | HARVONI WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 12 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 8 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | FOR TREATMENT-NAIVE GENOTYPE 1 PATIENTS, APPROVAL WILL BE FOR 12 WEEKS. FOR THE SUB-GROUP OF PATIENTS THAT ARE TREATMENT-NAIVE GENOTYPE 1 WITHOUT CIRRHOSIS WHO HAVE PRE-TREATMENT HCV RNA LESS THAN 6 MILLION IU/ML, PRESCRIBERS MAY ELECT TO USE 8 WEEKS OF THERAPY IN LIEU OF 12 WEEKS. FOR TREATMENT-EXPERIENCED GENOTYPE 1 PATIENTS WITH CIRRHOSIS, APPROVAL WILL BE FOR 12 WEEKS IN COMBINATION WITH RIBAVIRIN. PATIENTS WITH DOCUMENTED INTOLERANCE OR CONTRAINDICATION TO RIBAVIRIN WILL BE APPROVED FOR 24 WEEKS AS MONOTHERAPY. INTOLERANCE OR CONTRAINDICATION TO RIBAVIRIN IS DEFINED AS NEUTROPHILS LESS THAN 750 CELLS/MM3 WITHIN THE PAST MONTH, HEMOGLOBIN LESS THAN 10G/DL WITHIN THE PAST MONTH, PLATELETS LESS THAN 50,000 CELLS/MM3 WITHIN THE PAST MONTH, OR AUTOIMMUNE HEPATITIS OR OTHER AUTOIMMUNE CONDITION KNOWN TO BE EXACERBATED BY |

| PA Criteria | Criteria Details |
| --- | --- |
| | RIBAVIRIN. FOR OFF- LABEL HARVONI REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# HETLIOZ

## Products Affected

- Hetlioz

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS URINARY MELATONIN AND/OR CORTISOL LEVELS OR ACTIGRAPHY OVER A SEVERAL WEEK INTERVAL), OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A SLEEP SPECIALIST OR NEUROLOGIST. |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | HETLIOZ WILL BE COVERED FOR A DIAGNOSIS OF NON-24-HOUR SLEEP-WAKE DISORDER FOR BLIND INDIVIDUALS WHO LACK LIGHT PERCEPTION. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS |

# HORIZANT

## Products Affected

- Horizant oral tablet extended release 300 mg, 600 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR THE TREATMENT OF POST-HERPETIC NEURALGIA, THERE MUST BE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF GENERIC GABAPENTIN. FOR THE TREATMENT OF RESTLESS LEGS SYNDROME, THERE MUST BE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF IMMEDIATE-RELEASE ROPINIROLE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# HUMIRA

## Products Affected

- Humira Pediatric Crohns Start
- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Psor-Uv-Adol HS
- Humira(CF) Pen subcutaneous pen injector kit 40 mg/0.4 mL
- Humira(CF) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | PATIENT MUST NOT HAVE A CONTRAINDICATION TO TNF THERAPY. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, DERMATOLOGIST, RHEUMATOLOGIST, OR OPTHALMOLOGIST DEPENDING ON THE CONDITION BEING TREATED |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | HUMIRA IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS. PSORIASIS- COVERED FOR PATIENTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% OF THEIR BODY SURFACE AREA. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS IN PATIENTS WITH LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. PATIENT ALSO MUST MEET ONE OF THE FOLLOWING CRITERIA (REQMT BYPASSED IF PATIENT HAS TRIED UVB AND COAL TAR OR PUVA AND TOPICAL CORTICOSTEROIDS--A NONPART- D SERVICE): 1) HAD A 3 |

| PA Criteria | Criteria Details |
| --- | --- |
| | MONTH TRIAL OF ACITRETIN, METHOTREXATE, OR CYCLOSPORINE THERAPY RESULTING IN INTOLERANCE OR CLINICAL FAILURE OR 2) HAVE TRIED AND FAILED AT LEAST 2 OF THE FOLLOWING FOR 3 MONTHS: TREATMENT WITH MEDIUM AND/OR HIGH POTENCY TOPICAL CORTICOSTEROIDS OR ANTHRALIN, CALCIPOTRIENE, OR TAZAROTENE. ANKYLOSING SPONDYLITIS- IN PATIENTS WITH REFRACTORY DISEASE DEFINED BY FAILURE OF AT LEAST ONE NSAID FOR AT LEAST 1 MONTH EACH. RHEUMATOID ARTHRITIS- IN PATIENTS WITH ACTIVE MODERATE TO SEVERE RA WHO HAVE FAILED TO RESPOND TO AND/OR IS INTOLERANT TO APPROVED DISEASE-MODIFYING ANTIRHEUMATIC DRUG (DMARD) AGENTS, SUCH AS METHOTREXATE, AZATHIOPRINE, SULFASALAZINE, OR HYDROXYCHLOROQUINE, EITHER ALONE OR IN COMBINATION FOR A 3 MONTH PERIOD. COVERED FOR A DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE. IN ADDITION, THE PATIENT MUST MEET ONE OF THE FOLLOWING CRITERIA: 1) PATIENT CONTINUES TO EXPERIENCE DISEASE FLARE DESPITE COMPLETE AND ADEQUATE THERAPY WITH A CORTICOSTEROID. 2) TREATMENT WITH AN IMMUNOMODULATOR (SUCH AS AZATHIOPRINE OR 6-MP) FAILS TO MAINTAIN REMISSION IN A CASE OFSTEROID DEPENDENT OR STEROID REFRACTORY DISEASE. 3) DOCUMENTATION IS PROVIDED THAT AZATHIOPRINE, 6-MP, OR METHOTREXATE IS NOT EFFECTIVE, CONTRAINDICATED, OR NOT TOLERATED. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERELY ACTIVE JUVENILE IDIOPATHIC ARTHRITIS. THE PATIENT MUST HAVE FAILED TO RESPOND TO AND/OR IS INTOLERANT TO APPROVED DMARD AGENTS, SUCH AS METHOTREXATE, NSAIDS, ANALGESICS OR CORTICOSTEROIDS, EITHER ALONE OR IN COMBINATION. COVERED FOR THE DIAGNOSIS OF ULCERATIVE COLITIS IN PATIENTS WITH DOCUMENTED FAILURE OF TWO CLASSES: THIOPURINE, 5-AMINOSALYICYLATE, CYCLOSPORINE, OR IV/ORAL STEROIDS. COVERED FOR A DIAGNOSIS OF MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA. COVERED FOR A DIAGNOSIS OF NON-INFECTIOUS INTERMEDIATE, POSTERIOR UVEITIS AND PANUVEITIS IN PTS WITH AN INEFFECTIVE RESPONSE, CONTRAINDICATION, OR INTOLERANCE TO TWO OF THE FOLLOWING THREE REGIMENS 1) TOPICAL OR INJECTED OPHTHALMOLOGIC STEROID 2) ORAL SYSTEMIC STEROID 3) IMMUNOSUPPRESSIVE AGENT, SUCH AS AZATHIOPRINE, MYCOPHENOLATE, OR METHOTREXATE . REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# ILUMYA

## Products Affected

- Ilumya

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A DERMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE AREA (BSA). COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. IN ADDITION, THERE MUST BE DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# INCRELEX

## Products Affected

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | INCRELEX WILL NOT BE COVERED FOR GROWTH PROMOTION IN PATIENTS WITH CLOSED EPIPHYSES OR AS A SUBSTITUTE FOR GROWTH HORMONE REPLACEMENT THERAPY. IV ADMINISTRATION WILL NOT BE COVERED |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS IGF-1 LEVELS AND GH LEVELS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE 2 YEARS OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST, PEDIATRIC ENDOCRINOLOGIST, OR NEPHROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | INCRELEX WILL BE COVERED IN PATIENTS WITH SEVERE PRIMARY IGF-1 DEFICIENCY DEFINED AS HEIGHT SD SCORE LESS -3.0, BASAL IGF-1 SD SCORE LESS THAN -3.0, AND NORMAL OR ELEVATED GH. THEY WILL ALSO BE COVERED IN PATIENTS WITH GROWTH HORMONE (GH) GENE DELETION WITH THE DEVELOPMENT OF NEUTRALIZING ANTIBODIES TO GH. NORMAL DOSE IS 40-120MCG/KG SQ TWICE DAILY GIVEN 20 MINUTES BEFORE OR AFTER A MEAL OR SNACK TO AVOID HYPOGLYCEMIA. DOSES GREATER THAN 120MCG/KG WILL NOT BE COVERED. |

# INGREZZA

## Products Affected

- Ingrezza oral capsule 40 mg, 80 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST OR PSYCHIATRIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# INJECTABLE ONCOLOGY

## Products Affected

- Sylatron
- Synribo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS (IF APPLICABLE). WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ONCOLOGIST OR HEMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS WILL BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF LABEL USE REQUIREMENTS. |

# IVIG

## Products Affected

- Bivigam
- Carimune NF Nanofiltered intravenous recon soln 6 gram
- Flebogamma DIF intravenous solution 10 %
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked injection solution 1 gram/10 mL (10 %)
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C injection solution 1 gram/10 mL (10 %)
- Octagam
- Panzyga
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED UNDER PART D IF INTRAVENOUS IMMUNE GLOBULIN (IVIG) IS PROVIDED IN THE HOME FOR INDIVIDUAL WITH DIAGNOSIS OF PRIMARY IMMUNE DEFICIENCY DISEASE. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS (IF APPLICABLE). WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS FOR CHRONIC CONDITIONS. ONE MONTH FOR ACUTE CONDITIONS. 5 DAYS FOR GUILLAIN-BARRE |
| **Other Criteria** | REQUESTS WILL BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF LABEL USE REQUIREMENTS. |

# JUBLIA

## Products Affected

- Jublia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS KOH STAIN OR CULTURE RESULTS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | UNLESS CONTRAINDICATED, JUBLIA WILL BE COVERED FOR THE DIAGNOSIS OF ONYCHOMYCOSIS WHEN THERE IS DOCUMENTATION OF FAILURE OR SEVERE INTOLERANCE TO A COURSE OF ORAL TERBINAFINE. |

# JUXTAPID

## Products Affected

- Juxtapid

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NOT COVERED IN PTS WITH AST/ALT GREATER THAN 2 TIMES ULN. WILL NOT BE APPROVED IN COMBINATION WITH KYNAMRO OR REPATHA. |
| **Required Medical Information** | DIAGNOSIS, LAB/DIAGNOSTIC TEST RESULTS (MUST INCLUDE BASELINE LDL LEVEL), CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST |
| **Coverage Duration** | INITIAL COVERAGE FOR 26 WEEKS. AFTER THE 26-WK APPROVAL, RECERT WILL OCCUR AT 1-YEAR INTERVALS. |
| **Other Criteria** | CLINICAL DIAGNOSIS WILL BE BASED ON INCLUSION CRITERIA FOR CLINICAL TRIAL: DOCUMENTED FUNCTIONAL MUTATION IN BOTH LDL RECEPTOR ALLELES OR SKIN FIBROBLAST LDL RECEPTOR ACTIVITY MORE THAN 20% OF NORMAL, OR UNTREATED TOTAL CHOLESTEROL MORE THAN 500 MG/DL AND TRIGLYCERIDES LESS THAN 300 MG/DL AND BOTH PARENTS WITH DOCUMENTED TOTAL CHOLESTEROL MORE THAN 250 MG/DL. BASELINE LDL MUST BE GREATER THAN 130 DESPITE USE OF THE FOLLOWING COMBINATION OF MODERATE DOSE (ATORVASTATIN 40 OR EQUIVALENT) HIGH-POTENCY STATIN (ATORVASTATIN, ROSUVASTATIN, PITAVASTATIN, SIMVASTATIN) WITH ANOTHER LIPID LOWERING AGENT. FOR PATIENTS WITH A CONTRAINDICATION OR INTOLERANCE TO STATIN THERAPY, THE USE OF OTHER LIPID LOWERING AGENTS WILL MEET THIS PREREQUISITE REQUIREMENT. DOCUMENTATION OF LACK OF RESPONSE OR SEVERE INTOLERANCE TO REPATHA IS REQUIRED. INITIAL APPROVAL WILL BE 26 WEEKS. FURTHER APPROVAL WILL REQUIRE EVIDENCE OF IMPROVEMENT OVER |

| PA Criteria | Criteria Details |
| --- | --- |
| | BASELINE LDL LEVEL. IF LDL LEVEL MEETS RECERTIFICATION REQUIREMENTS, THEN THE REQUEST WILL BE REVIEWED ANNUALLY THEREAFTER. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# JYNARQUE

## Products Affected

- Jynarque

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEPHROLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD). ADPKD MUST BE RAPIDLY PROGRESSING, AS DEFINED BY EITHER 1) CONFIRMED GFR DECLINE OF AT LEAST 5 ML/MIN/1.73 M2 PER YEAR OVER 1 YEAR AND/OR 2.5 ML/MIN/1.73 M2 PER YEAR OVER A PERIOD OF 5 YEARS OR 2) TOTAL KIDNEY VOLUME INCREASE OF AT LEAST 5% PER YEAR CONFIRMED BY REPEATED ULTRASOUND OR MRI MEASUREMENTS TAKEN AT LEAST 6 MONTHS APART. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | COVERAGE WILL BE EXCLUDED IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508 DEL MUTATION IN THE CFTR GENE. |
| **Required Medical Information** | DIAGNOSIS, LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING FOR CFTR GENE MUTATION THAT IS RESPONSIVE TO IVACAFTOR |
| **Age Restrictions** | FOR THE ORAL GRANULE PACKETS, PATIENT MUST BE 2 YEARS OF AGE OR OLDER. FOR THE ORAL TABLETS, PATIENT MUST BE 6 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# KERYDIN

## Products Affected

- Kerydin

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS KOH STAIN OR CULTURE RESULTS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | UNLESS CONTRAINDICATED, KERYDIN WILL BE COVERED FOR THE DIAGNOSIS OF ONYCHOMYCOSIS WHEN THERE IS DOCUMENTATION OF FAILURE OR SEVERE INTOLERANCE TO A COURSE OF ORAL TERBINAFINE. |

# KEVEYIS

## Products Affected

- Keveyis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NEUROLOGIST OR GENETICIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# KEVZARA

## Products Affected

- Kevzara subcutaneous syringe

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A RHEUMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR.REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# KINERET

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A RHEUMATOLOGIST (FOR DIAGNOSIS OF RHEUMATOID ARTHRITIS OR NOMID) OR PEDIATRICIAN (DIAGNOSIS OF NOMID ONLY) |
| **Coverage Duration** | TWO YEARS FOR RA. ONE YEAR FOR NOMID. |
| **Other Criteria** | KINERET IS COVERED FOR THE TREATMENT OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS FOR PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR. COVERED FOR THE DIAGNOSIS OF NEONATAL-ONSET MULTISYSTEM INFLAMMATORY DISEASE (NOMID). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# KORLYM

## Products Affected

- Korlym

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED IN PATIENTS WHO ARE PREGNANT, WHO HAVE A HISTORY OF UNEXPLAINED VAGINAL BLEEDING/ENDOMETRIAL CHANGES, WHO ARE CURRENTLY RECEIVING LONGTERM CORTICOSTEROIDS, OR WHO ARE CURRENTLY ON SIMVASTATIN, LOVASTATIN OR A MEDICATION THAT IS A CYP3A SUBSTRATE AND HAS A NARROW THERAPEUTIC RANGE. |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS HBA1C LEVELS AND NEGATIVE PREGNANCY TEST IN WOMEN OF CHILDBEARING AGE), AND DOCUMENTATION OF PREVIOUS THERAPIES (FAILURE OF SURGERY OR NOT A CANDIDATE FOR SURGERY). |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED IN PATIENTS WITH A DIAGNOSIS OF ENDOGENOUS CUSHINGS SYNDROME AND TYPE 2 DIABETES OR GLUCOSE INTOLERANCE. PATIENTS MUST HAVE FAILED SURGERY OR NOT BE A CANDIDATE FOR SURGERY. WOMEN OF CHILDBEARING AGE MUST HAVE A NEGATIVE PREGNANCY TEST PRIOR TO STARTING THERAPY AND MUST NOT BE NURSING. NON-HORMONAL CONTRACEPTION MUST BE USED WHILE ON THERAPY. HYPOKALEMIA SHOULD BE CORRECTED PRIOR TO TREATMENT AND MONITORED FOR DURING TREATMENT. PATIENTS SHOULD ALSO BE CLOSELY MONITORED FOR SIGNS AND SYMPTOMS OF ADRENAL INSUFFICIENCY. RECERTIFICATION AFTER ONE YEAR WILL |

| PA Criteria | Criteria Details |
| --- | --- |
| | REQUIRE THE SUBMISSION OF PATIENT PROGRESS NOTES AND LAB WORK THAT DEMONSTRATES CLINICAL RESPONSE OR STABILIZATION OF DISEASE. INDIVIDUALS MUST MAINTAIN A HEMOGLOBIN A1C THAT IS EQUAL TO OR LESS THAN BASELINE FOR CONTINUED APPROVAL. |

# KUVAN

## Products Affected

- Kuvan

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS GENETIC TEST RESULTS AND SERUM PHENYLALANINE LEVELS, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | INITIAL APPROVAL 2 MOS. RECERT EVERY 1 YR THEREAFTER |
| **Other Criteria** | KUVAN IS COVERED AS ADJUNCT THERAPY FOR MEMBERS DIAGNOSED WITH PHENYLKETONURIA (PKU). INITIAL APPROVAL WILL BE FOR 2 MONTHS. PHENYLALANINE (PHE) LEVELS SHOULD BE CHECKED ONE WEEK AFTER INITIATION OF THERAPY. IF PHE LEVELS DO NOT DECREASE FROM BASELINE ON A 10MG/KG/DAY DOSE, THE DOSE MAY BE INCREASED TO 20MG/KG/DAY. IF PHE LEVELS DO NOT DECREASE BY AT LEAST 30% FROM BASELINE AFTER 2 MONTHS, THE PATIENT IS CONSIDERED A NON-RESPONDER AND FURTHER THERAPY WITH KUVAN WILL NOT BE AUTHORIZED. |

# KYNAMRO

## Products Affected

- Kynamro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | WILL NOT BE APPROVED IN COMBINATION WITH JUXTAPID |
| **Required Medical Information** | DIAGNOSIS, LAB/DIAGNOSTIC TEST RESULTS (MUST INCLUDE BASELINE LDL LEVEL), CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST |
| **Coverage Duration** | INITIAL COVERAGE FOR 26 WEEKS. AFTER THE 26-WK APPROVAL, RECERT WILL OCCUR AT 1-YEAR INTERVALS. |
| **Other Criteria** | CLINICAL DIAGNOSIS WILL BE BASED ON INCLUSION CRITERIA FOR CLINICAL TRIAL: GENETIC CONFIRMATION OF 2 MUTATED ALLELES AT THE LDL-R GENE LOCUS OR DOCUMENTED HISTORY OF UNTREATED LDL-C GREATER THAN 500 MG/DL AND AT LEAST ONE OF THE FOLLOWING: 1)TENDINOUS AND OR CUTANEOUS XANTHOMA PRIOR TO AGE 10, 2) LDL-C GREATER THAN 190 MG/DL IN BOTH PARENTS PRIOR TO LIPID LOWERING THERAPY, 3) IF PARENT DATA NOT AVAILABLE, HISTORY OF CAD IN A 1ST DEGREE MALE RELATIVE OF THE PARENTS YOUNGER THAN 55 OR 1ST DEGREE FEMALE RELATIVE YOUNGER THAN 60. BASELINE LDL MUST BE GREATER THAN 130 DESPITE USE OF THE FOLLOWING COMBINATION OF MODERATE DOSE (ATORVASTATIN 40 OR EQUIVALENT) HIGH-POTENCY STATIN (ATORVASTATIN, ROSUVASTATIN, PITAVASTATIN, SIMVASTATIN) WITH ANOTHER LIPID LOWERING AGENT.DOCUMENTATION OF LACK OF RESPONSE OR SEVERE INTOLERANCE TO REPATHA IS REQUIRED. INITIAL APPROVAL WILL BE 26 WEEKS. FURTHER APPROVAL WILL REQUIRE IMPROVEMENT OVER BASELINE LDL LEVEL. IF LDL LEVEL MEETS RECERTIFICATION |

| PA Criteria | Criteria Details |
| --- | --- |
| | REQUIREMENTS, THEN THE REQUEST WILL BE REVIEWED ANNUALLY THEREAFTER. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# LIDOCAINE PATCH

## Products Affected

- lidocaine topical adhesive patch,medicated
- ZTlido
- Lidoderm

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# MARINOL

## Products Affected

- dronabinol

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | FOR THE TREATMENT OF APPETITE LOSS SECONDARY TO AIDS, THE PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ANOREXIA DUE TO AIDS-1 YR. CHEMO-INDUCED NAUSEA, VOMITING-6 M. POST-OP NAUSEA, VOMITING-1 M. |
| **Other Criteria** | FOR THE PROPHYLAXIS OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY OR FOR THE PROPHYLAXIS OF POST-OPERATIVE NAUSEA AND VOMITING, THERE MUST BE A DOCUMENTED FAILURE OF ONE 5HT-3 RECEPTOR ANTAGONIST. THERE ARE NO ADDITIONAL REQUIREMENTS FOR PATIENTS WITH AIDS-ASSOCIATED LOSS OF APPETITE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# MAVYRET

## Products Affected

- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | MAVYRET WILL NOT BE COVERED IN PATIENTS WITH MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). MAYVRET WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 8-16 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | FOR OFF- LABEL MAVYRET REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# METFORMIN ER

## Products Affected

- metformin oral tablet,ER gast.retention 24 hr 1,000 mg, 500 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF TYPE-2 DIABETES. DOCUMENTATION OF CLINICAL FAILURE OR SEVERE INTOLERANCE OF BOTH GENERIC IMMEDIATE-RELEASE METFORMIN (EQUIVALENT OF GLUCOPHAGE) AND GENERIC EXTENDED-RELEASE METFORMIN (GENERIC EQUIVALENT OF GLUCOPHAGE XR OR FORTAMET) IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# METHAMPHETAMINE

## Products Affected

- methamphetamine

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED WHEN USED FOR WEIGHT LOSS, EVEN IF NON-COSMETIC (SUCH AS MORBID OBESITY) |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# MULPLETA

## Products Affected

- Mulpleta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A HEMATOLOGIST, GASTROENTEROLOGIST, OR HEPATOLOGIST |
| **Coverage Duration** | ONE MONTH |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF THROMBOCYTOPENIA DEFINED AS A PLATELET COUNT OF LESS THAN 50000 PLATELETS PER MICROLITER. IN ADDITION, THE PATIENT MUST HAVE A DIAGNOSIS OF CHRONIC LIVER DISEASE AND BE SCHEDULED TO UNDERGO A PROCEDURE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# MULTIPLE SCLEROSIS

## Products Affected

- Betaseron subcutaneous kit
- Extavia subcutaneous kit

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR THE STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR THE DIAGNOSIS OF MULTIPLE SCLEROSIS, DOCUMENTATION OF CLINICAL FAILURE OR SEVERE INTOLERANCE OF AVONEX, PLEGRIDY, OR REBIF IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# MYALEPT

## Products Affected

- Myalept

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | USE OF MYALEPT IS EXCLUDED FOR THE FOLLOWING CONDITIONS: METABOLIC DISEASE NOT ASSOCIATED WITH CONGENITAL LEPTIN DEFICIENCY, HIV-ASSOCIATED LIPODYSTROPHY |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF LEPTIN DEFICIENCY IN PATIENTS WITH CONGENITAL OR ACQUIRED GENERALIZED LIPODYSTROPHY. DIAGNOSIS IS CONFIRMED THROUGH LOW SERUM LEPTIN LEVELS AND THE ABSENCE OF SUBCUTANEOUS FAT. |

# MYTESI

## Products Affected

- Mytesi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | DRUG THERAPY WILL NOT BE AUTHORIZED FOR INDIVIDUALS WHO HAVE A HISTORY OF ULCERATIVE COLITIS, CROHNS DISEASE, CELIAC SPRUE, CHRONIC PANCREATITIS, MALABSORPTION, OR ANY OTHER GI DISEASE ASSOCIATED WITH DIARRHEA. |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE SYMPTOMATIC RELIEF OF NONINFECTIOUS DIARRHEA IN INDIVIDUALS WITH HIV/AIDS ON ANTI-RETROVIRAL THERAPY. IN ADDITION, DOCUMENTATION OF CLINICAL FAILURE TO EITHER LOPERAMIDE OR DIPHENOXYLATE IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# NAMZARIC

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | NAMZARIC WILL BE AUTHORIZED FOR PATIENTS WITH A DIAGNOSIS OF MODERATE TO SEVERE ALZHEIMER DISEASE. THERE MUST ALSO BE DOCUMENTED STABILIZATION ON DONEPEZIL FOR A MINIMUM OF THREE MONTHS IMMEDIATELY PRECEDING THE REQUEST FOR NAMZARIC. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# NATPARA

## Products Affected

- Natpara

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, LABORATORY VALUES AS INDICATED UNDER OTHER COVERAGE, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST. |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | NATPARA WILL BE AUTHORIZED AS ADJUNCT THERAPY TO CONTROL HYPOCALCEMIA IN PATIENTS WITH HYPOPARATHYROIDISM. HYPOPARATHYROIDISM WILL BE DEFINED AS HYPOCALCEMIA (CALCIUM CONCENTRATION BELOW THE LOWER LIMIT OF NORMAL) AND DOCUMENTED PARATHYROID LEVELS BELOW THE LOWER LIMIT OF NORMAL RANGE, RECORDED ON TWO SEPARATE OCCASIONS WITHIN THE PAST TWELVE MONTHS. DUE TO THE RISKS ASSOCIATED WITH THE USE OF NATPARA, THERE MUST BE CONFIRMED EVIDENCE OF VITAMIN D SUFFICIENCY. IF THE 25(OH) D LEVEL IS BELOW THE LOWER LIMIT OF NORMAL, TREATMENT WITH NATPARA WILL NOT BE AUTHORIZED UNTIL THE SERUM 25(OH) D LEVEL RETURNS TO NORMAL FROM THE DEFICIENT STATE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# NITYR

## Products Affected

- Nityr

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT THERAPIES, PERTINENT LAB/DIAGNOSTIC TEST RESULTS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | PENDING CMS APPROVAL |

# NORTHERA

## Products Affected

- Northera

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | ADMINISTRATION BY ANYONE OTHER THAN A HEALTHCARE PROFESSIONAL IS EXCLUDED. NUCALA WILL NOT BE COVERED FOR THE RELIEF OF ACUTE BRONCHOSPASM OR STATUS ASTHMATICUS. NUCALA WILL NOT BE APPROVED FOR GRANULOMATOSIS WITH POLYANGIITIS (ALSO KNOWN AS GPA OR WEGENERS GRANULOMATOSIS) OR MICROSCOPIC POLYANGIITIS. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TESTS USED TO CONFIRM DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES. FOR DIAGNOSIS OF EGPA, BASELINE BIRMINGHAM VASCULITIS ACTIVITY SCORE (BVAS) FROM WITHIN 4 WEEKS PRIOR TO START OF NUCALA THERAPY MUST ALSO BE PROVIDED |
| **Age Restrictions** | FOR TREATMENT OF SEVERE PERSISTENT ASTHMA WITH AN EOSINOPHILIC PHENOTYPE, PATIENT MUST BE 12 YEARS OF AGE OR OLDER. FOR TREATMENT OF EGPA, PT MUST BE 18 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | FOR ASTHMA WITH EOSINOPHILIC PHENOTYPE, MUST BE PRESCRIBED BY AN ALLERGIST/ IMMUNOLOGIST OR PULMONOLOGIST. FOR EGPA, MUST BE PRESCRIBED BY AN ALLERGIST/IMMUNOLOGIST, PULMONOLOGIST, NEUROLOGIST, OR RHEUMATOLOGIST. |
| **Coverage Duration** | INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER |
| **Other Criteria** | COVERED FOR THE TX OF SEV PERSISTENT ASTHMA W/ EOSINOPHILIC PHENOTYPE. PATIENT MUST HAVE A PERIPHERAL BLOOD EOSINOPHIL COUNT OF AT LEAST 150 CELLS/MICROLITER WITHIN PAST 6 WKS BEFORE NUCALA REQ OR AT LEAST 300 MICROLITER AT ANYTIME WITHIN THE PAST YEAR. ADULT PTS MUST HAVE A PRE-BRONCHODILATOR FEV1 OF LESS THAN 80 PERCENT PREDICTED. PTS AGED 12-18 YRS |

| PA Criteria | Criteria Details |
| --- | --- |
| | MUST HAVE A PRE-BRONCHODILATOR FEV1 OF LESS THAN 90 PERCENT PREDICTED OR FEV1/FVC LESS THAN 0.8. PT MUST BE MAINTAINED ON ASTHMA TX BASED ON THE NHLBI GUIDELINES, WHICH RECOMMEND THE COMBO OF A HI-DOSE INHALED STEROID WITH 1 OTHER CONTROLLER MED, SUCH AS A LABA, LEUKOTRIENE INHIBITOR, OR THEOPHYLLINE. CONSIDERATIONS ARE GIVEN FOR PTS UNABLE TO TOLERATE HI-DOSE INHALED STEROIDS OR HAVE A CONTRAINDICATION TO CONTROLLER MEDS INDICATED IN THE NHLBI GUIDELINES. IF ABOVE CRITERIA IS MET, COVERAGE WILL BE PROVIDED IF THE PT EXPERIENCED 2 OR MORE ASTHMA EXACERBATIONS (E.G., UNSCHEDULED DOCTOR/URGENT CARE/ER VISITS, HOSPITAL ADMIN, OR DOCUMENTED NEED FOR ACUTE SYSTEMIC STEROIDS) WITHIN THE PAST 12 MONTHS. UPON RECERT, DOCUMENTATION PROVIDED MUST VALIDATE REDUCTION IN ASTHMA EXACERBATIONS AS DEFINED ABOVE. COVERED FOR THE TX OF ADULT PTS WITH EGPA. PT MUST HAVE A DX OF RELAPSING OR REFRACTORY EGPA, EXISTING FOR AT LEAST THE PAST 6 MOS. PT MUST HAVE 1 OF THE FOLLOWING: 1) HX OF RELAPSE REQUIRING AN INCREASE IN GLUCOCORTICOID DOSE, INITIATION OR INCREASE IN OTHER IMMUNOSUPPRESSIVE TX, OR HOSPITALIZATION IN THE PAST 2 YRS WHILE RECEIVING AT LEAST 7.5 MG/DAY PREDNISONE (OR EQUIV) WITHIN THE PAST 6 MOS OR 2) PT MUST HAVE FAILED TO ACHIEVE REMISSION FOLLOWING A STANDARD INDUCTION REGIMEN ADMINISTERED FOR AT LEAST 3 MOS OR RECURRENCE OF SX OF EGPA WHILST TAPERING GLUCOCORTICOIDS. STANDARD TX REGIMENS MAY INC PREDNISONE (OR EQUIV) DOSED AT LEAST 7.5 MG/DAY IN COMBO WITH AN IMMUNOSUPPRESSANT DRUG (UNLESS CONTRAINDICATED). PT MUST HAVE A HX OR PRESENCE OF ASTHMA AND A BLOOD EOSINOPHIL LEVEL OF AT LEAST 10% OR AN ABS. EOSINOPHIL COUNT OF MORE THAN 1000 CELLS/MICROLITER WITHIN THE PAST 6 WKS. IN ADDITION, THERE MUST BE 2 OR MORE OF THE FOLLOWING: CONFIRMATION THROUGH BIOPSY, MOTOR DEFICIT OR NERVE CONDUCTION ABNORMALITY, PULMONARY INFILTRATES, SINONASAL ABNORMALITY, CARDIOMYOPATHY, GLOMERULONEPHRITIS, ALVEOLAR HEMORRHAGE, PALPABLE PURPURA, OR POSITIVE TEST FOR ANCA. LASTLY, THE PT MUST BE ON A STABLE DOSE OF ORAL CORTICOSTEROIDS (AT LEAST 7.5MG/DAY OF PREDNISONE OR EQUIV) FOR AT LEAST 4 WKS IMMEDIATELY BEFORE START OF NUCALA TX. UPON RECERT, PROVIDE DOCUMENTATION VALIDATING |

| PA Criteria | Criteria Details |
| --- | --- |
| | ATTAINMENT AND MAINTENANCE OF REMISSION WHILE ON NUCALA. REMISSION IS DEFINED AS BVAS EQUAL TO ZERO, WHILE MAINTAINED ON AN ORAL CS DOSE NO GREATER THAN 7.5 MG/DAY PREDNISONE (OR EQUIV). REQUESTS WILL BE EVALUATED FOR PART B VS D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQS. |

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# NUPLAZID

## Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg, 17 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | PER THE BLACK BOX WARNING ON NUPLAZID, ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. THEREFORE, NUPLAZID WILL NOT BE COVERED FOR ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS. |
| **Required Medical Information** | DIAGNOSIS, DIAGNOSTIC TEST RESULTS, CURRENT AND PREVIOUS THERAPIES FOR THE STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST, PSYCHIATRIST, OR GERIATRICIAN |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# NUVIGIL

## Products Affected

- armodafinil
- Nuvigil

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, PERTINENT DIAGNOSTIC TEST RESULTS (SUCH AS RESULTS OF A SLEEP STUDY), CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NARCOLEPSY/SHIFT WORK SLEEP DISORDER- MUST BE NEUROLOGIST OR SLEEP SPECIALIST. SLEEP APNEA- MUST BE NEUROLOGIST, SLEEP SPECIALIST OR PULMONOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ARMODAFINIL (NUVIGIL) IS COVERED FOR THE TREATMENT OF NARCOLEPSY, OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, AND SHIFT WORK SLEEP DISORDER. SHIFT WORK SLEEP DISORDER IS TYPICALLY ASSOCIATED WITH AT LEAST 5 SHIFTS PER MONTH (USUALLY NIGHT) THAT OCCUR DURING THE HABITUAL SLEEP PHASE CONTINUING OVER A PERIOD OF AT LEAST 3 MONTHS. IN ADDITION TO HAVING ONE OF THE ABOVE DIAGNOSES, THERE MUST ALSO BE DOCUMENTATION OF CLINICAL FAILURE OR SEVERE INTOLERANCE OF MODAFINIL (PROVIGIL). |

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | PATIENTS WITH COMPLETE BILIARY OBSTRUCTION WILL BE EXCLUDED FROM COVERAGE. |
| **Required Medical Information** | DIAGNOSIS, DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, PERTINENT LAB RESULTS (SUCH AS ALP LEVELS, BILIRUBIN, ANTIMICHONDRIAL ANTIBODY/AMA TEST) |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST OR HEPATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | OCALIVA WILL BE COVERED FOR THE DIAGNOSIS OF PRIMARY BILIARY CHOLANGITIS THAT HAS BEEN CONFIRMED BY 2 OF THE FOLLOWING: POSITIVE ANTIMICHONDRIAL ANTIBODIES (AMA), HISTORY OF INCREASED ALP LEVELS, OR LIVER BIOPSY CONSISTENT WITH PRIMARY BILIARY CHOLANGITIS. IN ADDITION, DOCUMENTATION MUST BE PROVIDED THAT THE PATIENT IS UNABLE TO TOLERATE URSODIOL (URSODEOXYCHOLIC ACID/UDCA) OR THAT THE PATIENT HAD AN INADEQUATE RESPONSE TO AT LEAST 12 MONTHS OF URSODIOL TREATMENT. INADEQUATE RESPONSE TO URSODIOL IS DEFINED AS ALP GREATER THAN 1.67 TIMES THE UPPER LIMIT OF NORMAL (ULN EQUALS 118 U/L FOR FEMALES AND 124 U/L FOR MALES) OR TOTAL BILIRUBIN LEVEL THAT IS GREATER THAN 1 TIME THE UPPER LIMIT OF NORMAL, BUT LESS THAN 2 TIMES UPPER LIMIT OF NORMAL (ULN EQUALS 1.1 MG/DL FOR FEMALES AND 1.5 MG/DL FOR MALES). FOR PATIENTS WHO ARE UNABLE TO TOLERATE URSODIOL, OCALIVA WILL BE COVERED AS MONOTHERAPY. FOR PATIENTS WHO HAD AN INADEQUATE RESPONSE TO |

| PA Criteria | Criteria Details |
| --- | --- |
| | URSODIOL, OCALIVA WILL BE COVERED WHEN PRESCRIBED IN COMBINATION WITH URSODIOL. UPON RECERTIFICATION, THERE MUST BE DOCUMENTATION OF ALP LESS THAN 1.67 TIMES THE ULN (AS DEFINED ABOVE), TOTAL BILIRUBIN LESS THAN OR EQUAL TO ULN (AS DEFINED ABOVE), AND AN ALP DECREASE OF AT LEAST 15%. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# OFEV

## Products Affected

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | OFEV WILL BE COVERED FOR A DOCUMENTED DIAGNOSIS OF IDIOPATHIC PULMONARY FIBROSIS. |

# OLUMIANT

## Products Affected

- Olumiant

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A RHEUMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE OF TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ORAL ONCOLOGY

## Products Affected

- Afinitor Disperz oral tablet for suspension 2 mg, 3 mg, 5 mg
- Afinitor oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg
- Alecensa
- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets,dose pack
- Bosulif oral tablet 100 mg, 400 mg, 500 mg
- Braftovi oral capsule 50 mg, 75 mg
- Cabometyx
- Calquence
- Caprelsa oral tablet 100 mg, 300 mg
- Cometriq
- Copiktra
- Cotellic
- Daurismo oral tablet 100 mg, 25 mg
- Erivedge
- Erleada
- Farydak
- Gilotrif
- Ibrance
- Iclusig
- Idhifa
- imatinib oral tablet 100 mg, 400 mg
- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet
- Inlyta oral tablet 1 mg, 5 mg
- Iressa
- Jakafi
- Kisqali
- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Lenvima oral capsule 10 mg/day (10 mg x 1), 12 mg/day (4 mg x 3), 14 mg/day(10 mg x 1-4 mg x 1), 18 mg/day (10 mg x 1-4 mg x2), 20 mg/day (10 mg x 2), 24 mg/day(10 mg x 2-4 mg x 1), 4 mg, 8 mg/day (4 mg x 2)
- Lonsurf oral tablet 15-6.14 mg, 20-8.19 mg
- Lorbrena oral tablet 100 mg, 25 mg
- Lynparza oral tablet
- Mekinist oral tablet 0.5 mg, 2 mg
- Mektovi
- Nerlynx
- Nexavar
- Ninlaro
- Odomzo
- Pomalyst
- Rubraca
- Rydapt
- Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg
- Stivarga
- Sutent
- Tafinlar
- Tagrisso
- Talzenna oral capsule 0.25 mg, 1 mg
- Tasigna
- Tibsovo
- Tykerb
- Venclexta oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack
- Verzenio
- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution
- Vizimpro
- Votrient
- Xalkori
- Xospata
- Xtandi
- Zejula
- Zelboraf
- Zolinza
- Zydelig
- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS (IF APPLICABLE). WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | FOR CANCER DIAGNOSIS, MUST BE PRESCRIBED BY AN ONCOLOGIST OR HEMATOLOGIST. FOR NON-CANCER DIAGNOSIS, MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST. |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# 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 |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | FOR DX OF RHEUMATOID ARTHRITIS, PATIENT MUST BE 18 YEARS OF AGE OR OLDER. FOR JUVENILE IDIOPATHIC ARTHRITIS, PATIENT MUST BE 2 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | PRESCRIBER MUST BE A RHEUMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PSORIATIC ARTHRITIS. COVERED FOR THE TREATMENT OF RHEUMATOID ARTHRITIS OR JUVENILE IDIOPATHIC ARTHRITIS IN PATIENTS. PATIENT MUST HAVE MODERATE TO SEVERELY ACTIVE POLYARTICULAR ARTHRITIS. THE PATIENT MUST HAVE FAILED TO RESPOND TO, OR IS INTOLERANT TO A DMARD, SUCH AS METHOTREXATE, AZATHIOPRINE, SULFASALAZINE, OF HYDROXYCHLOROQUINE, EITHER ALONE OR IN COMBINATION FOR A 3-MONTH PERIOD. ORENCIA MAY BE USED AS MONOTHERAPY OR IN COMBINATION WITH OTHER DMARDS. ORENCIA SHOULD NOT BE USED IN COMBINATION WITH TNF ANTAGONISTS OR OTHER BIOLOGICAL THERAPIES. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ORENITRAM

## Products Affected

- Orenitram oral tablet extended release
  0.125 mg, 0.25 mg, 1 mg, 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | FOR THE DIAGNOSIS OF PULMONARY HYPERTENSION, PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (RIGHT HEART CATHETERIZATION WHICH SHOWS MEAN PULMONARY ARTERY PRESSURE (PAP) OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION WHEN THE PATIENT HAS HAD A RIGHT HEART CATHETERIZATION WITH RESULTS AS LISTED IN THE REQUIRED MEDICAL INFORMATION SECTION. THERE MUST ALSO BE DOCUMENTATON OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GENERIC SILDENAFIL OR ADCIRCA AND AN ENDOTHELIN RECEPTOR ANTAGONIST SUCH AS LETAIRIS, TRACLEER, OR OPSUMIT EITHER ALONE OR IN COMBINATION. |

# ORFADIN

## Products Affected

- Orfadin

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS URINE ORGANIC ACIDS OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ORFADIN IS COVERED AS ADJUNCT THERAPY FOR MEMBERS DIAGNOSED WITH HEREDITARY TYROSINEMIA TYPE 1 CHARACTERIZED BUT NOT LIMITED TO: FAILURE TO THRIVE, HEPATOMEGALY IN THE FIRST 3 MONTHS OF LIFE, JAUNDICE, EPISTAXIS, MELENA, PURPURIC LESIONS, MARKED EDEMA, POLYNEUROPATHY OR PAINFUL ABDOMINAL CRISES AND PRESENCE OF URINARY SUCCINYLACETONE AS THE BIOCHEMICAL MARKER SUBSTANCE. |

# ORILISSA

## Products Affected

- Orilissa oral tablet 150 mg, 200 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR PATIENTS WITH SEVERE HEPATIC IMPAIRMENT (CHILD PUGH C) AND AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GYNECOLOGIST |
| **Coverage Duration** | DYSPAREUNIA/MODERATE HEPATIC IMPAIRMENT: 6 MOS MAX. OTHER: AUTH 6 MOS, RECERT 18 MOS. (24 MOS MAX) |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF PAIN ASSOCIATED WITH ENDOMETRIOSIS. IN ADDITION, THE PATIENT MUST HAVE A LACK OF CLINICAL RESPONSE, INTOLERANCE OR CONTRAINDICATION TO AT LEAST ONE PRESCRIPTION STRENGTH NONSTEROIDAL ANTI-INFLAMMATORY DRUG (NSAID) USED IN COMBINATION WITH HORMONAL THERAPY. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ORKAMBI

## Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | COVERAGE WILL BE EXCLUDED IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE NOT HOMOZYGOUS FOR THE F508 DEL MUTATION IN THE CFTR GENE. |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING THAT SHOWS TWO COPIES OF THE F508 DEL MUTATION IN THE CONDUCTANCE REGULATOR (CFTR) GENE. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# OSMOLEX ER

## Products Affected

- Osmolex ER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PARKINSON'S DISEASE OR DRUG-INDUCED EXTRAPYRAMIDAL REACTIONS. IN ADDITION, THE PATIENT MUST HAVE SIGNIFICANT INTOLERANCE, THERAPEUTIC FAILURE, OR CONTRAINDICATION TO IMMEDIATE-RELEASE AMANTADINE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# OSTEOPOROSIS

## Products Affected

- Forteo
- Prolia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS (REFER TO OTHER CRITERIA SECTION) |
| **Other Criteria** | PATIENT MUST FALL INTO ONE OF THE FOLLOWING CATEGORIES: POSTMENOPAUSAL WOMAN, PRIMARY HYPOGONADOL OSTEOPOROSIS IN A MALE OR PATIENT AT RISK FOR STEROID INDUCED OSTEOPOROSIS. PATIENT MUST ALSO BE AT HIGH RISK FOR A FRACTURE DEFINED AS 1) HISTORY OF PREVIOUS OSTEOPOROSIS-RELATED FRACTURE, 2) T- SCORE OF -2.5 SD OR LESS, 3) T-SCORE BETWEEN -1.0 AND -2.5 SD BELOW NORMAL AND A FRAX SCORE FOR HIP FRACTURE OF 3% OR GREATER OR THE RISK FOR OTHER BONE FRACTURE IS 20% OR GREATER. PATIENT MUST ALSO HAVE EXPERIENCED SEVERE INTOLERANCE, THERAPEUTIC FAILURE, OR HAVE A CONTRAINDICATION TO ORAL BISPHOSPHONATE THERAPY DEFINED AS: INTOLERANCE SUCH AS CHEST PAIN, DIFFICULTY IN SWALLOWING, INTENSE ABDOMINAL PAIN, OR CHRONIC DYSPEPSIA, WHEN ORAL BISPHOSPHONATE THERAPY WAS TAKEN ACCORDING TO MANUFACTURER RECOMMENDATIONS, OR PATIENT IS BED-RIDDEN/UNABLE TO SIT UPRIGHT FOR 30 MINUTES UNSUPERVISED, OR PATIENT HAS ESOPHAGEAL ULCERATIONS, ESOPHAGEAL STRICTURE, BARRETT'S ESOPHAGITIS, OR ACTIVE ULCERS, OR PATIENT |

| PA Criteria | Criteria Details |
| --- | --- |
| | EXPERIENCED A FRACTURE OR DECREASE IN BMD WHILE ON ORAL BISPHOSPHONATE THERAPY. PROLIA WILL BE COVERED TO INCREASE BONE MASS IN MEN AT HIGH RISK OF FRACTURE RECEIVING ANDROGEN DEPRIVATION THERAPY (BILATERAL ORCHIECTOMY OR GNRH-AGONIST THERAPY) FOR NON-METASTATIC PROSTATE CANCER. FOR THIS INDICATION, THE EXPECTED DURATION OF ANDROGEN DEPRIVATION THERAPY MUST BE AT LEAST 12 MONTHS. IN ADDITION, THE PATIENT MUST HAVE A T-SCORE AT LUMBAR SPINE, TOTAL HIP, OR FEMORAL NECK OF LESS THAN -1.0 OR A HISTORY OF OSTEOPOROTIC FRACTURE.PROLIA WILL BE COVERED TO INCREASE BONE MASS IN WOMEN AT HIGH RISK OF FRACTURE RECEIVING ADJUVANT AROMATASE INHIBITOR THERAPY FOR BREAST CANCER. FOR THIS INDICATION, THE PATIENT MUST BE DIAGNOSED WITH HORMONE RECEPTOR POSITIVE BREAST CANCER AND UNDERGOING TREATMENT WITH AN AROMATASE INHIBITOR, SUCH AS ANASTRAZOLE/ARIMIDEX, EXEMASTANE/AROMASIN, AND LETROZOLE/FEMARA. IN ADDITION, THE PATIENT MUST HAVE A T-SCORE AT LUMBAR SPINE, TOTAL HIP, OR FEMORAL NECK OF LESS THAN -1.0 OR A HISTORY OF OSTEOPOROTIC FRACTURE. THE FDA-APPROVED LABELING DOES NOT RECOMMEND THE USE OF PARATHYROID HORMONE ANALOGS (FORTEO ONLY) FOR THERAPY EXCEEDING A CUMULATIVE DURATION OF TWO YEARS. REQUEST WILL ALSO BE EVALUATED FOR PART B VERSUS PART D COVERAGE AND OFF-LABEL USE. |

# OTEZLA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | PRESCRIBER MUST BE A DERMATOLOGIST OR RHEUMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | OTEZLA IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS. OTEZLA IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE AREA. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS IN PATIENTS WITH LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. PATIENTS ALSO MUST MEET ONE OF THE FOLLOWING CRITERIA: 1) HAD A 3 MONTH TRIAL OF ACITRETIN, METHOTREXATE, OR CYCLOSPORINE THERAPY RESULTING IN INTOLERANCE OR CLINICAL FAILURE OR 2) HAVE TRIED UVB/COAL TAR OR PUVA/TOPICAL CORTICOSTEROIDS FOR AT LEAST 3 MONTHS OR 3) HAVE TRIED AND FAILED AT LEAST TWO OF THE FOLLOWING FOR 3 MONTHS: TREATMENT WITH MEDIUM AND/OR HIGH POTENCY TOPICAL CORTICOSTEROIDS OR ANTHRALIN, CALCIPOTRIENE, OR TAZAROTENE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED |

| PA Criteria | Criteria Details |
| --- | --- |
| | ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# OXERVATE

## Products Affected

- Oxervate

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN OPHTHALMOLOGIST |
| **Coverage Duration** | 8 WEEKS |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF STAGE 2 (PERSISTENT EPITHELIAL DEFECT, PED) OR STAGE 3 (CORNEAL ULCER) NEUROTROPHIC KERATITIS (NK). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# PAIN MANAGEMENT

## Products Affected

- Abstral
- Actiq
- fentanyl citrate
- Fentora
- Lazanda
- Subsys sublingual spray,non-aerosol 100 mcg/spray, 200 mcg/spray, 400 mcg/spray, 600 mcg/spray, 800 mcg/spray

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE MANAGEMENT OF BREAKTHROUGH PAIN IN INDIVIDUALS WITH CANCER THAT ARE OPIOD-TOLERANT. IN ADDITION, THERE MUST BE DOCUMENTATION OF FAILURE OR SEVERE INTOLERANCE TO AT LEAST TWO OTHER OPIOID MEDICATIONS |

# PALYNZIQ

## Products Affected

- Palynziq

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, SERUM PHENYLALANINE LEVELS, AND ANY OTHER PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS GENETIC TEST RESULTS) PERFORMED TO CONFIRM THE DIAGNOSIS. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A HEALTHCARE PROVIDER EXPERIENCED IN THE MANAGEMENT OF PKU |
| **Coverage Duration** | INITIAL APPROVAL 1 YEAR. RECERT EVERY 2 YRS THEREAFTER |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF PHENYLKETONURIA (PKU) WITH HYPERPHENYLALANEMIA (HPA). IN ADDITION TO DIAGNOSIS, THERE MUST BE DOCUMENTATION OF ELEVATED BLOOD PHENYALANINE LEVEL (GREATER THAN 600 MICRO-MOL PER LITER). PATIENT MUST HAVE FAILED TO RESPOND TO TREATMENT WITH KUVAN (SAPROPTERIN) FOR A PERIOD OF NO LESS THAN 30 DAYS. UPON RECERTIFICATION, COVERAGE WILL NOT BE EXTENDED FOR PATIENTS WHO HAVE NOT RESPONDED TO THERAPY. RESPONSE TO THERAPY IS DEFINED AS AT LEAST A 20 PERCENT REDUCTION IN BLOOD PHENYLALANINE CONCENTRATION FROM PRE-TREATMENT BASELINE OR A BLOOD PHENYLALANINE CONCENTRATION LESS THAN OR EQUAL TO 600 MICRO-MOL PER LITER AFTER AT LEAST 16 WEEKS OF CONTINUOUS TREATMENT WITH THE MAXIMUM TOLERATED DOSE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# PRALUENT

## Products Affected

- Praluent Pen

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TESTS TO INCLUDE A FASTING BASELINE LDL LEVEL TAKEN WITHIN 30 DAYS PRIOR TO PRALUENT TREATMENT REQUEST. FOR THE DIAGNOSIS OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEREMIA (HEFH), DOCUMENTATION MUST INCLUDE ALL INFORMATION REQUIRED TO CALCULATE A DEFINITE SCORE USING THE WORLD HEALTH ORGANIZATION CRITERIA (DUTCH LIPID NETWORK) OR SIMON-BROOME REGISTER DIAGNOSTIC CRITERIA. ALTERNATELY, IF THE RESULTS OF MOLECULAR GENERIC TESTING ARE AVAILABLE, PLEASE SUBMIT FOR REVIEW. A CONFIRMED DIAGNOSIS OF HEFH CAN BE VALIDATED UTILIZING ONE OF THESE THREE METHODS: A DEFINITE SCORE USING THE WORLD HEALTH ORGANIZATION CRITERIA, A DEFINITE SCORE USING THE SIMON-BROOME REGISTER CRITERIA OR MOLECULAR GENETIC TESTING. ONLY ONE DIAGNOSTIC METHOD IS REQUIRED. FOR ALL DIAGNOSES, DOCUMENTATION OF PREVIOUS OR CONCURRENT STATIN THERAPIES AND THE OUTCOME OF THOSE TRIALS IS REQUIRED. UPON RECERTIFICATION, THE RESULTS OF A FASTING LDL-C LEVEL TAKEN AFTER 4-8 WEEKS ON TREATMENT MUST BE SUBMITTED FOR REVIEW. |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST |
| **Coverage Duration** | INITIAL APPROVAL IS 12 WEEKS. REFER TO OTHER CRITERIA FOR RECERTIFICATION GUIDELINES. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | FOR ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), PT MUST HAVE A HX OF ACUTE CORONARY SYNDROME, MI, ANGINA, ARTERIAL REVASCULARIZATION, STROKE, TIA, PAD, OR OTHER ATHEROSCLEROTIC DISEASE. FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH), DX MUST BE DEFINITE PER THE DUTCH LIPID NETWORK OR SIMON-BROOME REGISTER DIAGNOSTIC CRITERIA. PRALUENT THERAPY SHOULD BE CONSIDERED IF THE PT IS HAS BEEN UNABLE TO REACH LDL GOAL FOR ASCVD OR EXCEEDS THE LDL INITIATION THRESHOLD FOR HEFH AS DEFINED BELOW, DESPITE TREATMENT WITH A HI-INTENSITY STATIN (ATORVASTATIN 40 MG, CRESTOR 20 MG) FOR A PERIOD OF AT LEAST 8 WKS. FOR STATIN INELIGIBLE PTS (DEFINED BELOW), TREAMENT WITH HI-INTENSITY STATIN THERAPY WILL NOT BE REQUIRED. FOR ASCVD, LDL GOAL IS LESS THAN OR EQUAL TO 70 MG/DL. FOR HEFH, PRALUENT TX MAY BE INITIATED IF THE PTS LDL IS GREATER THAN OR EQUAL TO 100MG/DL. STATIN INELIGIBILITY DEFINED AS A CONTRAINDICATION TO STATIN, STATIN-INDUCED RHABDOMYOLYSIS, OR STATIN INTOLERANCE. STATIN INTOLERANCE DEFINED AS THE TRIAL OF AT LEAST 2 DIFFERENT STATINS (1 WHICH IS HYDROPHILIC, SUCH AS FLUVASTATIN, PRAVASTATIN, CRESTOR) WITH CONFIRMED STATIN-RELATED ADVERSE EFFECTS (MUSCLE-RELATED SX) OR BIOMARKER ABNORMALITIES (ALT/AST, BILIRUBIN ELEVATIONS). WITH DOSE REDUCTION OR D/C IN STATIN TRIALS, ADVERSE EFFECTS RESOLVED AND/OR BIOMARKER ABNORMALITIES RETURNED TO NORMAL.PRALUENT WILL NOT BE APPROVED IN COMBO WITH JUXTAPID OR KYNAMRO. FOR STATIN ELIGIBLE PTS, AUTH WILL BE GRANTED FOR 12 WKS IN COMBO WITH THE MAX TOLERATED DOSE OF A STATIN. FOR STATIN INELIGIBLE PTS, AUTH WILL BE GRANTED FOR 12 WKS. AT 12 WKS, AN AUTH WILL BE GRANTED FOR 1 YR FOR A DIAGNOSIS OF ASCVD OR HEFH, IF THERE IS ADEQUATE REDUCTION IN LDL LEVELS, DEFINED AS A REDUCTION IN LDL VERSUS BASELINE . AT WK 12, IF THERE IS INADEQUATE LDL REDUCTION WHILE ON LOWER DOSE PRALUENT, THEN 12 MORE WKS OF TX WILL BE AUTHORIZED TO ASSESS THE IMPACT OF DOSE INCREASE. AT 24 WKS, AUTH WILL NOT BE EXTENDED IF THERE IS INADEQUATE REDUCTION IN LDL. IF ADEQUATE LDL LEVELS ARE MAINTAINED, THEN RECERT WILL OCCUR EVERY 1 YR. |

# PROMACTA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# PROVIGIL

## Products Affected

- modafinil
- Provigil

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, PERTINENT DIAGNOSTIC TEST RESULTS (SUCH AS RESULTS OF A SLEEP STUDY), CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST OR SLEEP SPECIALIST FOR A DIAGNOSIS OF NARCOLEPSY OR SHIFT WORK SLEEP DISORDER. MUST BE PRESCRIBED BY A NEUROLOGIST, SLEEP SPECIALIST, OR PULMONOLOGIST FOR A DIAGNOSIS OF SLEEP APNEA. |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | PROVIGIL IS COVERED FOR THE TREATMENT OF NARCOLEPSY, OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, AND SHIFT WORK SLEEP DISORDER. SHIFT WORK SLEEP DISORDER IS TYPICALLY ASSOCIATED WITH AT LEAST 5 SHIFTS PER MONTH (USUALLY NIGHT) THAT OCCUR DURING THE HABITUAL SLEEP PHASE CONTINUING OVER A PERIOD OF AT LEAST 3 MONTHS. FOR THE DRUG DEX COMPENDIA-SUPPORTED INDICATION OF AUGMENTATION THERAPY FOR THE TREATMENT OF DEPRESSION, PROVIGIL WILL BE COVERED WHEN THE PATIENT HAS TRIED AT LEAST 2 DIFFERENT ANTIDEPRESSANTS. FOR THE DRUGDEX COMPENDIA-SUPPORTED INDICATION OF ADHD, PROVIGIL WILL BE COVERED IN PATIENTS WHO HAVE HAD SEVERE INTOLERANCE OR THERAPEUTIC FAILURE TO TWO DIFFERENT MEDICATIONS APPROVED FOR THE TREATMENT OF |

| PA Criteria | Criteria Details |
| --- | --- |
| | ATTENTION DEFICIT DISORDER, SUCH AS METHYLPHENIDATE, AMPHETAMINE SALT, OR ATOMOXETINE. |

# PULMONARY HYPERTENSION

## Products Affected

- Adcirca
- Alyq
- Letairis
- Opsumit
- Revatio oral suspension for reconstitution
- Revatio oral tablet
- sildenafil (Pulmonary Arterial Hypertension) oral
- Tracleer oral tablet
- Tracleer oral tablet for suspension
- Ventavis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (RIGHT HEART CATHETERIZATION WHICH SHOWS MEAN PULMONARY ARTERY PRESSURE OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST). |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION WHEN THE PATIENT HAS HAD A RIGHT HEART CATHETERIZATION WITH RESULTS AS LISTED IN THE REQUIRED MEDICAL INFORMATION SECTION. FOR ADULT PATIENTS, DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE TO GENERIC SILDENAFIL OR ADCIRCA IS REQUIRED PRIOR TO APPROVAL FOR LETAIRIS, TRACLEER, REVATIO, AND OPSUMIT. PREREQUISITE THERAPY WITH SILDENAFIL OR ADCIRCA IS NOT REQUIRED FOR PEDIATRIC PATIENTS. NEBULIZED PRODUCTS WILL ALSO BE EVALUATED FOR PART B VERSUS PART D COVERAGE. |

# PULMOZYME

## Products Affected

- Pulmozyme

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE AT 5 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERAGE UNDER MEDICARE PART B WILL BE EVALUATED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# QUALAQUIN

## Products Affected

- Qualaquin
- quinine sulfate

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | TREATMENT OF LEG CRAMPS IS EXCLUDED. |
| **Required Medical Information** | DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | 6 MONTHS |
| **Other Criteria** | QUALAQUIN IS COVERED FOR THE TREATMENT OF MALARIA INFECTIONS |

# QUDEXY XR

## Products Affected

- Qudexy XR
- topiramate oral capsule,sprinkle,ER 24hr

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | FOR A SEIZURE DIAGNOSIS, PATIENT MUST HAVE DOCUMENTATION OF FAILURE OR SEVERE INTOLERANCE TO TWO GENERIC ANTICONVULSANT MEDICATIONS, ONE OF WHICH IS GENERIC TOPIRAMATE. GENERIC ANTICONVULSANT MEDICATIONS INCLUDE CARBAMAZEPINE, DIVALPROEX SODIUM, LAMOTRIGINE, LEVETIRACETAM, PHENYTOIN, OXCARBAZEPINE, AND VARIOUS OTHERS AS APPROPRIATE FOR THE SEIZURE DIAGNOSIS IN QUESTION. FOR MIGRAINE PROPHYLAXIS, PATIENT MUST HAVE DOCUMENTED FAILURE OR SEVERE INTOLERANCE TO GENERIC TOPIRAMATE. |

# RAVICTI

## Products Affected

- Ravicti

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY PHYSICIAN EXPERIENCED IN THE MANAGEMENT OF UREA CYCLE DISORDERS |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# RELISTOR

## Products Affected

- Relistor oral
- Relistor subcutaneous solution
- Relistor subcutaneous syringe

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF OPIOD-INDUCED CONSTIPATION WITH DOCUMENTED LACK OF RESPONSE OR SEVERE INTOLERANCE TO MOVANTIK. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TESTS TO INCLUDE A FASTING BASELINE LDL LEVEL TAKEN WITHIN 30 DAYS PRIOR TO REPATHA TREATMENT REQUEST. FOR THE DIAGNOSIS OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEREMIA (HEFH), DOCUMENTATION MUST INCLUDE ALL INFORMATION REQUIRED TO CALCULATE A DEFINITE SCORE USING THE WORLD HEALTH ORGANIZATION CRITERIA (DUTCH LIPID NETWORK) OR SIMON-BROOME REGISTER DIAGNOSTIC CRITERIA. ALTERNATELY, IF THE RESULTS OF MOLECULAR GENETIC TESTING ARE AVAILABLE, PLEASE SUBMIT FOR REVIEW. A CONFIRMED DIAGNOSIS OF HEFH CAN BE VALIDATED UTILIZING ONE OF THESE THREE METHODS: A DEFINITE SCORE USING THE WORLD HEALTH ORGANIZATION CRITERIA, A DEFINITE SCORE USING THE SIMON-BROOME REGISTER CRITERIA OR MOLECULAR GENETIC TESTING. ONLY ONE DIAGNOSTIC METHOD IS REQUIRED. FOR THE DIAGNOSIS OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEREMIA (HOFH), DIAGNOSIS MUST BE CONFIRMED WITH MOLECULAR GENETIC TESTING OR PT MUST HAVE A HX OF AN UNTREATED LDL LEVEL GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YRS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS OR HAVE UNTREATED TOTAL CHOLESTEROL GREATER THAN 500 MG/DL AND BOTH PARENTS WITH DOCUMENTED UNTREATED TOTAL CHOLESTEROL GREATER THAN 250MG/DL. ONLY ONE DIAGNOSTIC METHOD IS REQUIRED. FOR ALL DIAGNOSES, DOCUMENTATION OF PREVIOUS OR CONCURRENT STATIN THERAPIES AND THE OUTCOME OF THOSE TRIALS IS REQUIRED. UPON RECERTIFICATION, THE RESULTS OF A FASTING LDL-C LEVEL |

| PA Criteria | Criteria Details |
|---|---|
| | TAKEN AFTER 4-8 WEEKS ON TREATMENT MUST BE SUBMITTED FOR REVIEW. |
| **Age Restrictions** | FOR THE DIAGNOSIS OF ASCVD OR HEFH, THE PATIENT MUST BE 18 YEARS OF AGE OR OLDER. FOR THE DIAGNOSIS OF HOFH THE PATIENT MUST BE 13 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST |
| **Coverage Duration** | INITIAL APPROVAL IS FOR 12 WKS. AFTER THE 12 WK APPROVAL, RECERT WILL OCCUR AT 1-YEAR INTERVALS. |
| **Other Criteria** | FOR ASCVD, PT MUST HAVE A HX OF ACS, MI, ANGINA, ARTERIAL REVASCULARIZATION, STROKE, TIA, PAD, OTHER ATHEROSCLEROTIC DISEASE. FOR HEFH, DEFINITE DX PER THE DUTCH LIPID NETWORK OR SIMON-BROOME REGISTER DIAGNOSTIC CRITERIA REQUIRED. FOR HOFH, DX MUST BE CONFIRMED WITH GENETIC TESTING OR PT MUST HAVE A HX OF AN UNTREATED LDL LEVEL GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YRS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS OR HAVE UNTREATED TOTAL CHOLESTEROL GREATER THAN 500 MG/DL AND BOTH PARENTS WITH DOCUMENTED UNTREATED TOTAL CHOLESTEROL GREATER THAN 250MG/DL. REPATHA TX SHOULD BE CONSIDERED IF THE PT HAS BEEN TREATED WITH A HI-INTENSITY STATIN (ATORVASTATIN 40 MG, CRESTOR 20 MG) FOR A PERIOD OF AT LEAST 8 WKS AND IS UNABLE TO REACH LDL GOAL FOR ASCVD OR EXCEEDS THE LDL INITIATION THRESHOLD FOR HEFH OR HOFH AS DEFINED BELOW. FOR STATIN INELIGIBLE PTS (DEFINED BELOW), TREAMENT WITH HI-INTENSITY STATIN THERAPY WILL NOT BE REQUIRED. FOR ASCVD, LDL GOAL IS LESS THAN OR EQUAL TO 70 MG/DL. FOR HEFH OR HOFH, REPATHA TX MAY BE INITIATED IF THE PTS LDL IS GREATER THAN OR EQUAL100MG/DL. STATIN INELIGIBILITY DEFINED AS CONTRAINDICATION TO STATINS, STATIN-INDUCED RHABDOMYOLYSIS OR STATIN INTOLERANCE. STATIN INTOLERANCE DEFINED AS THE TRIAL OF 2 STATINS (1 MUST BE FLUVASTATIN, PRAVASTATIN, OR CRESTOR) WITH CONFIRMED STATIN-RELATED ADVERSE EFFECTS (MUSCLE-RELATED SX) OR PRESENCE OF LAB ABNORMALITIES (ALT/AST, BILIRUBIN ELEVATIONS). WITH DOSE REDUCTION OR D/C IN STATIN TRIALS, ADVERSE EFFECTS RESOLVED |

| PA Criteria | Criteria Details |
| --- | --- |
| | AND/OR LAB ABNORMALITIES RETURNED TO NORMAL.REPATHA WILL NOT BE APPROVED IN COMBO WITH JUXTAPID OR KYNAMRO. AUTHORIZATION WILL BE FOR AN INITIAL 12 WKS. AT WK 12, IF THERE IS A REDUCTION IN LDL VERSUS BASELINE FOR ASCVD, HEFH, or HOFH, THEN RECERTIFICATION WILL OCCUR EVERY 1 YR THEREAFTER. |

# REXULTI

## Products Affected

- Rexulti oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES. |
| **Age Restrictions** | MUST BE 18 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERAGE OF REXULTI FOR A DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER REQUIRES DOCUMENTATION OF SIGNIFICANT INTOLERANCE OR THERAPEUTIC FAILURE OF AN ANTIDEPRESSANT (SUCH AS AN SSRI, SNRI, TCA)AND A GENERIC ATYPICAL ANTIPSYCHOTIC INDICATED FOR MAJOR DEPRESSIVE DISORDER (SUCH AS ARIPIRAZOLE, OLANZAPINE, QUETIAPINE). COVERAGE FOR THE DIAGNOSIS OF SCHIZOPHRENIA REQUIRES DOCUMENTATION OF SIGNIFICANT INTOLERANCE OR THERAPEUTIC FAILURE OF ONE FIRST LINE TREATMENT (SUCH AS RISPERIDONE, OLANZAPINE, ZIPRASIDONE, QUETIAPINE). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# RUCONEST

## Products Affected

- Ruconest

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR THE PROPHYLAXIS OF HEREDITARY ANGIOEDEMA ATTACKS. EXCLUDED FOR THE TREATMENT OF ACUTE LARYNGEAL HEREDITARY ANGIOEDEMA ATTACKS. |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND LABORATORY TESTS USED TO CONFIRM DIAGNOSIS, AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE 13 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III FOR THE TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACKS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SAMSCA

## Products Affected

- Samsca

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SHINGRIX

## Products Affected

- Shingrix (PF)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR INDIVIDUALS UNDER THE AGE OF 50 |
| **Required Medical Information** | DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | PA APPLIES FOR PATIENTS AGED 50 AND YOUNGER ONLY |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS. FOR THE DIAGNOSIS OF CUSHINGS DISEASE, THERE MUST BE PERTINENT LAB/DIAGNOSTIC TEST RESULTS, WHICH INCLUDE A MEAN URINE FREE CORTISOL (MUFC) LEVEL AT BASELINE AND UPON RECERTIFICATION. THERE MUST BE DOCUMENTATION OF PREVIOUS THERAPIES, WHICH INDICATE THAT THE PATIENT IS NOT A CANDIDATE FOR SURGERY OR HAS EXPERIENCED TREATMENT FAILURE WITH A PREVIOUS SURGERY. A NON-SURGICAL CANDIDATE IS DEFINED AS EITHER HAVING A MEDICAL CONTRAINDICATION TO SURGERY OR HAVING A TUMOR WHICH IS SURGICALLY UNAPPROACHABLE. |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST |
| **Coverage Duration** | INITIAL COVERAGE IS FOR 3 MONTHS. ONE YEAR THEREAFTER |
| **Other Criteria** | AFTER 3 MONTHS OF THERAPY FOR A DIAGNOSIS OF CUSHINGS DISEASE, PATIENT MUST DEMONSTRATE A REDUCTION IN MUFC COMPARED TO BASELINE. SUBSEQUENT AUTHORIZATIONS WILL BE FOR TWELVE MONTHS WITH CONTINUED SIGNS OF EFFICACY. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SILIQ

## Products Affected

- Siliq

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A DERMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% BODY SURFACE AREA (BSA). COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS THAT INVOLVES LESS THAN 5% BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. IN ADDITION, THERE MUST BE DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SIMPONI

## Products Affected

- Simponi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | PRESCRIBER MUST BE A GASTROENTEROLOGIST FOR THE TREATMENT OF ULCERATIVE COLITIS. ALL OTHER INDICATIONS CAN BE PRESCRIBED BY A DERMATOLOGIST OR RHEUMATOLOGIST. |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | SIMPONI IS COVERED FOR THE DIAGNOSIS OF ANKYLOSING SPONDYLITIS IN PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA. SIMPONI IS COVERED FOR THE DIAGNOSIS OF THE RHEUMATOID ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, XELJANZ/XELJANZ XR. SIMPONI IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS IN PATIENTS WITH DOCUMENTED FAILURE OF TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, ORENCIA, STELARA, XELJANZ/XELJANZ XR. SIMPONI IS COVERED FOR THE DIAGNOSIS OF ULCERATIVE COLITIS IN PATIENTS WITH A DOCUMENTED FAILURE OF BOTH HUMIRA AND XELJANZ. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SIVEXTRO

## Products Affected

- Sivextro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS BACTERIAL CULTURES OR ANTIBIOTIC SENSITIVITY TESTING), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENTS MUST BE AT LEAST 18 YEARS OLD |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | 6 DAYS |
| **Other Criteria** | SIVEXTRO IS COVERED WHEN PRESCRIBED OR RECOMMENDED BY AN INFECTIOUS DISEASE SPECIALIST. WHEN PRESCRIBED BY ANY OTHER PRESCRIBER, LABORATORY DATA INCLUDING CULTURE SITE, ORGANISM IDENTIFIED AND SUSCEPTIBILITY MUST ACCOMPANY PRIOR-AUTHORIZATION REQUEST AND DOCUMENTATION MUST SUPPORT THE TRIAL. IN ADDITION, DOCUMENTATION OF THERAPEUTIC FAILURE OF AT LEAST ONE FIRST-LINE ANTIBACTERIAL AGENT THAT IS CLINICALLY APPROPRIATE FOR THE ORGANISM IDENTIFIED MUST BE SUBMITTED. APPROVAL WILL BE FOR 6 DAYS OF THERAPY. REQUESTS FOR NON-FDA APPROVED DURATIONS OF THERAPY WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SOVALDI

## Products Affected

- Sovaldi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | SOVALDI WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA-APPROVED INDICATION, COMPENDIA, OR AASLD/IDSA GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 12 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 TO 48 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF HARVONI OR MAVYRET OR EPCLUSA TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO HARVONI OR MAVYRET OR EPCLUSA. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# SPRITAM

## Products Affected

- Spritam oral tablet for suspension 1,000 mg, 250 mg, 500 mg, 750 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 4 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR SEIZURE DISORDERS WITH DOCUMENTATION OF LACK OF RESPONSE OR SEVERE INTOLERANCE TO AT LEAST TWO GENERIC ANTICONVULSANT MEDICATIONS, ONE OF WHICH IS A GENERIC LEVETIRACETAM DOSAGE FORM (IMMEDIATE-RELEASE, EXTENDED-RELEASE, OR SOLUTION). GENERIC ANTICONVULSANT MEDICATIONS INCLUDE CARBAMAZEPINE, DIVALPROEX SODIUM, LAMOTRIGINE, PHENYTOIN, OXCARBAZEPINE, AND OTHERS AS APPROPRIATE FOR THE SEIZURE DIAGNOSIS IN QUESTION. |

# STELARA

## Products Affected

- Stelara subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, DERMATOLOGIST, OR RHEUMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF PSORIATIC ARTHRITIS. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS WITH PSORIASIS THAT INVOLVES AT LEAST 5% OF THEIR BODY SURFACE AREA. FOR THOSE PATIENTS WITH LESS THAN 5% BODY SURFACE AREA INVOLVEMENT, CONSIDERATION WILL BE GIVEN TO THOSE WHO HAVE SEVERE DISEASE OF THE HANDS OR FEET OR OTHER AREAS CAUSING DISRUPTION IN NORMAL ACTIVITIES. PATIENTS ALSO MUST MEET ONE OF THE FOLLOWING CRITERIA 1) HAVE TRIED UVB/COAL TAR OR PUVA/TOPICAL CORTICOSTEROIDS FOR AT LEAST 3 MONTHS OR 2) HAVE TRIED AND FAILED AT LEAST TWO OF THE FOLLOWING FOR 3 MONTHS: TREATMENT WITH MEDIUM AND/OR HIGH POTENCY TOPICAL CORTICOSTEROIDS OR ANTHRALIN, CALCIPOTRIENE, OR TAZAROTENE. WHILE NOT REQUIRED, ADDITIONAL CONSIDERATION WILL BE GIVEN FOR PATIENTS WHO ATTEMPTED THERAPY WITH ACITRETIN, METHOTREXATE, OR CYCLOSPORINE RESULTING IN INTOLERANCE OR CLINICAL FAILURE. COVERED FOR A DIAGNOSIS OF MODERATELY TO |

| PA Criteria | Criteria Details |
| --- | --- |
| | SEVERELY ACTIVE CROHN'S DISEASE. IN ADDITION, THE PATIENT MUST MEET ONE OF THE FOLLOWING CRITERIA: 1) PATIENT CONTINUES TO EXPERIENCE DISEASE FLARE DESPITE COMPLETE AND ADEQUATE THERAPY WITH A CORTICOSTEROID. 2) TREATMENT WITH AN IMMUNOMODULATOR (SUCH AS AZATHIOPRINE OR 6-MP) FAILS TO MAINTAIN REMISSION IN A CASE OF STEROID-DEPENDENT OR STEROID-REFRACTORY DISEASE. 3) DOCUMENTATION IS PROVIDED THAT AZATHIOPRINE, 6-MP, OR METHOTREXATE IS NOT EFFECTIVE, CONTRAINDICATED, OR NOT TOLERATED. FOR PATIENTS WITH A DIAGNOSIS OF PSORIASIS WEIGHING LESS THAN OR EQUAL TO 100KG, 45MG DOSE WILL BE APPROVED. FOR PATIENTS WITH A DIAGNOSIS OF PSORIASIS WEIGHING GREATER THAN 100KG, 90MG DOSE WILL BE APPROVED. FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS, 45MG DOSE WILL BE APPROVED INITIAL DOSING FOR PSORIASIS AND PSORIATIC ARTHRITIS IS AT WEEKS 0, 4, 12 AND THEN EVERY 12 WEEKS THEREAFTER. FOR PATIENTS WITH COEXISTENT PSORIATIC ARTHRITIS AND MODERATE TO SEVERE PLAQUE PSORIASIS AND WHO WEIGH MORE THAN 100KG, A 90MG STARTING DOSE WILL BE AUTHORIZED. INITIAL DOSING IS AT WEEKS 0, 4, 12 AND THEN EVERY 12 WEEKS THEREFAFTER. FOR PATIENTS WITH CHROHN'S DISEASE, WEIGHT-DEPENDENT INDUCTION DOSING AT WEEK ZERO AND THE MAINTENANCE DOSE OF 90MG EVERY 8 WEEKS THEREAFTER WILL BE AUTHORIZED. |

# SULFONYLUREAS

## Products Affected

- chlorpropamide
- glyburide micronized
- glyburide oral tablet 1.25 mg, 2.5 mg, 5 mg
- glyburide-metformin oral tablet 1.25-250 mg, 2.5-500 mg, 5-500 mg
- Glynase

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PA APPLIES FOR PATIENTS AGE 65 AND OLDER. PA DOES NOT APPLY FOR PATIENTS AGE 64 AND YOUNGER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | THE AMERICAN GERIATRICS SOCIETY PUBLISHES THE BEERS CRITERIA FOR POTENTIALLY INAPPROPRIATE MEDICATIONS USED IN THE ELDERLY. GLYBURIDE AND CHLORPROPAMIDE ARE BOTH INCLUDED ON THE BEERS LIST. COVERAGE WILL BE PROVIDED FOR GLYBURIDE OR CHLORPROPAMIDE WITH DOCUMENTATION OF LACK OF EFFICACY OR INTOLERABLE SIDE EFFECTS TO BOTH GLIPIZIDE/GLIPIZIDE ER AND GLIMEPIRIDE (EITHER ALONE OR IN COMBINATION THERAPY WITH OTHER ANTI-DIABETIC MEDICATIONS). |

# SYMDEKO

## Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | COVERAGE WILL BE EXCLUDED IN PATIENTS THAT LACK THE REQUIRED GENETIC MUTATION(S) TARGETED BY THE MEDICATION |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING THAT SHOWS EITHER TWO COPIES OF THE F508 DEL MUTATION IN THE CONDUCTANCE REGULATOR (CFTR) GENE OR AT LEAST ONE MUTATION IN THE CFTR GENE THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR (SYMDEKO) BASED ON IN VITRO DATA AND/OR CLINICAL EVIDENCE. RESPONSIVE MUTATIONS INCLUDE: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3AG, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5GA, 3272-26AG, 3849+10KBCT |
| **Age Restrictions** | PATIENT MUST BE 12 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SYMPROIC

## Products Affected

- Symproic

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE TREATMENT OF OPIOD-INDUCED CONSTIPATION WITH DOCUMENTED LACK OF RESPONSE OR SEVERE INTOLERANCE TO MOVANTIK. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# SYNDROS

## Products Affected

- Syndros

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS. FOR A DIAGNOSIS OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY, ALSO LIST PREVIOUS THERAPIES. |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ANOREXIA DUE TO AIDS-1 YR. CHEMO-INDUCED NAUSEA, VOMITING-6 M. |
| **Other Criteria** | COVERED FOR THE TREATMENT OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY WITH DOCUMENTED LACK OF RESPONSE OR SEVERE INTOLERANCE TO ONE 5HT-3 RECEPTOR ANTAGONIST. COVERED FOR TREATMENT OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TAKHZYRO

## Products Affected

- Takhzyro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR ACUTE HEREDITARY ANGIOEDEMA ATTACKS |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III. PROPHYLACTIC THERAPY WITH TAKHZYRO WILL BE COVERED IN INDIVIDUALS WITH AT LEAST ONE SEVERE EPISODE OF ANGIOEDEMA PER MONTH. IN ADDITION, THE PATIENT MUST HAVE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF STEROIDS OR DANAZOL.REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TALTZ

## Products Affected

- Taltz Autoinjector
- Taltz Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A DERMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5 PERCENT BODY SURFACE AREA BSA. COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES LESS THAN 5 PERCENT BSA IF THE AFFECTED AREA INVOLVES THE HANDS, FEET, FACIAL OR GENITAL REGIONS. IN ADDITION, THERE MUST BE DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES, COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA. TALTZ IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS WITH DOCUMENTED FAILURE OF TWO OF THE FOLLOWING ALTERNATIVES, COSENTYX, ENBREL, HUMIRA, OTEZLA, ORENCIA, STELARA, XELJANZ, XELJANZ XR. REQUESTS FOR NON FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF LABEL USE REQUIREMENTS. |

# TAVALISSE

## Products Affected

- Tavalisse

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A HEMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF CHRONIC IMMUNE THROMBOCYTOPENIA PURPURA (ITP). IN ADDITION, THE PATIENT MUST HAVE EXPERIENCED AN INSUFFICIENT RESPONSE TO PREVIOUS TREATMENT, DEFINED AS A PLATELET COUNT OF LESS THAN 20000 PER MICROLITER OR GREATER THAN 20000 PER MICROLITER BUT WITH BLEEDING SYMPTOMS. PREVIOUS TREATMENTS MUST INCLUDE TWO OF THE FOLLOWING 1) CORTICOSTEROIDS, 2) IMMUNOGLOBULIN (IVIG), 3) RITUXIMAB OR SPLENECTOMY. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TECHNIVIE

## Products Affected

- Technivie

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | TECHNIVIE WILL NOT BE COVERED IN PATIENTS WITH MODERATE TO SEVERE HEPATIC IMPAIRMENT (CHILD PUGH C). TECHNIVIE WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA-APPROVED INDICATION, COMPENDIA, OR AASLD/IDSA GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF HARVONI OR MAVYRET OR EPCLUSA TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO HARVONI OR MAVYRET OR EPCLUSA. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# TEGSEDI

## Products Affected

- Tegsedi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED IN PATIENTS WITH A PLATELET COUNT LESS THAN 100 X 10 TO THE 9TH PER LITER OR HISTORY OF ACUTE GLOMERULONEPHRITIS CAUSED BY TEGSEDI |
| **Required Medical Information** | DIAGNOSIS WITH CONFIRMATION OF THE TRANSTHYRETIN (TTR) GENE MUTATION |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A SPECIALIST EXPERIENCED IN THE DIAGNOSIS OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (HATTR), SUCH AS A HEMATOLOGIST, ONCOLOGIST, NEUROLOGIST, GASTROENTEROLOGIST, GENETICIST, OR NEPHROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR TREATMENT OF POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (HATTR) WHEN THE DIAGNOSIS HAS BEEN CONFIRMED BY MUTATION OF THE TRANSTHYRETIN (TTR) GENE. PATIENTS MUST ALSO HAVE SYMPTOMS CONSISTENT WITH POLYNEUROPATHY, WHICH CAN INCLUDE EITHER PERIPHERAL SENSORIMOTOR POLYNEUROPATHY SYMPTOMS (SUCH AS TINGLING OR INCREASED PAIN IN THE HANDS/FEET/ARMS, LOSS OF FEELING IN THE HANDS/FEET, NUMBNESS OR TINGLING IN THE WRISTS, CARPAL TUNNEL SYNDROME, LOSS OF ABILITY TO SENSE TEMPERATURE, DIFFICULTY WITH FINE MOTOR SKILLS, WEAKNESS IN THE LEGS, DIFFICULTY WALKING, SEIZURES, HEADACHES) OR AUTONOMIC NEUROPATHY SYMPTOMS (SUCH AS ORTHOSTASIS, ABNORMAL SWEATING, SEXUAL |

| PA Criteria | Criteria Details |
| --- | --- |
| | DYSFUNCTION, RECURRENT URINARY TRACT INFECTION, DYSAUTONOMIC SYMPTOMS OF CONSTIPATION, DIARRHEA, NAUSEA, VOMITING, ANOREXIA, AND EARLY SATIETY). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# THALOMID

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TOPICAL RETINOIDS

## Products Affected

- adapalene topical cream
- adapalene topical gel
- adapalene topical solution
- Altreno
- Atralin
- Avita
- Differin topical cream
- Differin topical gel 0.1 %
- Differin topical gel with pump
- Differin topical lotion
- Fabior
- Plixda
- Retin-A
- Retin-A Micro
- Retin-A Micro topical gel with pump 0.06 %, 0.08 %
- tazarotene
- Tazorac
- tretinoin microspheres topical gel
- tretinoin topical

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED WHEN USED FOR COSMETIC PURPOSES |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ADAPALENE, TAZAROTENE, AND TRETINOIN PRODUCTS WILL BE APPROVED FOR THE DIAGNOSIS OF ACNE VULGARIS. IN ADDITION, TAZORAC WILL BE APPROVED FOR THE DIAGNOSIS OF PLAQUE PSORIASIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TREMFYA

## Products Affected

- Tremfya subcutaneous syringe

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A DERMATOLOGIST OR RHEUMATOLOGIST |
| **Coverage Duration** | TWO YEARS |
| **Other Criteria** | COVERED FOR THE DIAGNOSIS OF MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS THAT INVOLVES AT LEAST 5% OF BODY SURFACE AREA. FOR THOSE PATIENTS WITH LESS THAN 5% BODY SURFACE AREA INVOLVEMENT, CONSIDERATION WILL BE GIVEN TO THOSE WHO HAVE SEVERE DISEASE OF THE HANDS OR FEET OR OTHER AREAS CAUSING DISRUPTION IN NORMAL ACTIVITIES. . IN ADDITION, THERE MUST BE DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# TROKENDI XR

## Products Affected

- Trokendi XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | FOR A SEIZURE DIAGNOSIS, PATIENT MUST HAVE DOCUMENTATION OF FAILURE OR SEVERE INTOLERANCE TO TWO GENERIC ANTICONVULSANT MEDICATIONS, ONE OF WHICH IS GENERIC TOPIRAMATE. GENERIC ANTICONVULSANT MEDICATIONS INCLUDE CARBAMAZEPINE, DIVALPROEX SODIUM, LAMOTRIGINE, LEVETIRACETAM, PHENYTOIN, OXCARBAZEPINE, AND VARIOUS OTHERS AS APPROPRIATE FOR THE SEIZURE DIAGNOSIS IN QUESTION. FOR MIGRAINE PROPHYLAXIS, PATIENT MUST HAVE DOCUMENTED FAILURE OR SEVERE INTOLERANCE TO GENERIC TOPIRAMATE. |

# TYMLOS

## Products Affected

- Tymlos

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | TWO YEARS (REFER TO OTHER CRITERIA SECTION) |
| **Other Criteria** | COVERED FOR POST-MENOPAUSAL WOMEN AT HIGH RISK FOR FRACTURE. THE PATIENT MUST BE CONSIDERED HIGH RISK FOR FRACTURE, WHICH IS DEFINED AS 1) HISTORY OF PREVIOUS OSTEOPOROSIS-RELATED FRACTURE, 2) T- SCORE OF -2.5 SD OR LESS, 3) T-SCORE BETWEEN -1.0 AND -2.5 SD BELOW NORMAL AND A FRAX SCORE FOR HIP FRACTURE OF 3% OR GREATER OR THE RISK FOR OTHER BONE FRACTURE IS 20% OR GREATER. PATIENT MUST ALSO HAVE EXPERIENCED THERAPEUTIC FAILURE, SEVERE INTOLERANCE OR A CONTRAINDICATION TO AN ORAL BISPHOSPHONATE OR BE AN INAPPROPRIATE CANDIDATE FOR ORAL BISPHOSPHONATE THERAPY BASED ON CLINICAL PRESENTATION. THERAPEUTIC FAILURE IS DEFINED AS A DECREASE IN BONE MINERAL DENSITY OR A FRACTURE WHILE ON BIPHOSPHONATE THERAPY. SEVERE INTOLERANCE DEFINED AS CHEST PAIN, DIFFICULTY SWALLOWING, INTENSE ABDOMINAL PAIN OR CHRONIC DYSPEPSIA WHEN ORAL BISPHOSPHONATE THERAPY WAS TAKEN ACCORDING TO MANUFACTURER RECOMMENDATIONS. ORAL BISPHOSPHONATES MAY BE CLINICALLY INAPPROPRIATE FOR A PATIENT THAT IS BED- |

| PA Criteria | Criteria Details |
| --- | --- |
| | RIDDEN/UNABLE TO SIT UPRIGHT FOR 30 MINUTES UNSUPERVISED OR HAS ESOPHAGEAL ULCERATIONS, ESOPHAGEAL STRICTURE, BARRETT'S ESOPHAGITIS, OR ACTIVE ULCERS. THE FDA-APPROVED LABELING DOES NOT RECOMMEND THE USE OF PARATHYROID HORMONE ANALOGS FOR THERAPY EXCEEDING A CUMULATIVE DURATION OF TWO YEARS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# UCERIS FOAM

## Products Affected

- Uceris rectal

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST |
| **Coverage Duration** | INITIAL APPROVAL WILL BE FOR 6 WEEKS. SUBSEQUENT COURSES WILL BE AUTHORIZED AT 6 WEEK INTERVALS. |
| **Other Criteria** | UCERIS FOAM WILL BE AUTHORIZED FOR PATIENTS WITH A DIAGNOSIS OF ACTIVE, MILD TO MODERATE ULCERATIVE COLITIS WITH DOCUMENTATION OF SEVERE INTOLERANCE OR THERAPEUTIC FAILURE TO MESALAMINE ENEMAS, MESALAMINE SUPPOSITORIES, OR HYDROCORTISONE ENEMAS. THE INITIAL APPROVAL WILL BE FOR SIX WEEKS. AS TOPICAL BUDESONIDE DOES NOT HAVE PROVEN EFFICACY TO MAINTAIN REMISSION, CHRONIC THERAPY WITH UCERIS FOAM WILL NOT BE AUTHORIZED. APPROVAL FOR FUTURE TREATMENT COURSES WILL REQUIRE DOCUMENTATION OF REMISSION FROM THE INITIAL COURSE OF THERAPY. IN ADDITION, DOCUMENTATION THAT REMISSION FAILED ON A COURSE OF AN APPROPRIATE IMMUNOMODULATOR OR BIOLOGIC WILL BE REQUIRED. IF THE CRITERIA IS MET, SUBSEQUENT TREATMENT COURSES WILL A BE APPROVED IN 6 WEEK INTERVALS. REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE. |

# UPTRAVI

## Products Affected

- Uptravi oral tablet 1,000 mcg, 1,200 mcg, 1,400 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg
- Uptravi oral tablets,dose pack

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | FOR THE DIAGNOSIS OF PULMONARY HYPERTENSION, PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (RIGHT HEART CATHETERIZATION WHICH SHOWS MEAN PULMONARY ARTERY PRESSURE (PAP) OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST. |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION WHEN THE PATIENT HAS HAD A RIGHT HEART CATHETERIZATION WITH RESULTS AS LISTED IN THE REQUIRED MEDICAL INFORMATION SECTION. THERE MUST ALSO BE DOCUMENTATON OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GENERIC SILDENAFIL OR ADCIRCA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, AND DOCUMENTATION OF PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ONCOLOGIST OR DERMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# VIEKIRA AND VIEKIRA XR

## Products Affected

- Viekira Pak
- Viekira XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | VIEKIRA XR WILL NOT BE COVERED IN PATIENTS WITH MODERATE TO SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C). VIEKIRA XR WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA-APPROVED INDICATION, COMPENDIA, OR AASLD/IDSA GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF HARVONI OR MAVYRET OR EPCLUSA TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO HARVONI OR MAVYRET OR EPCLUSA. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | VOSEVI WILL NOT BE COVERED IN PATIENTS WITH MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). VOSEVI WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 WEEKS |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF MAVYRET TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO MAVYRET. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# VRAYLAR

## Products Affected

- Vraylar oral capsule
- Vraylar oral capsule,dose pack

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERAGE OF VRAYLAR FOR A DIAGNOSIS OF BIPOLAR DISORDER OR SCHIZOPHRENIA REQUIRES DOCUMENTATION OF SIGNIFICANT INTOLERANCE OR THERAPEUTIC FAILURE OF ONE FIRST LINE TREATMENT (SUCH AS RISPERIDONE, OLANZAPINE, ZIPRASIDONE, QUETIAPINE). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, DERMATOLOGIST, OR RHEUMATOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF MODERATE TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS FOR PATIENTS WHO HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO METHOTREXATE AS MONOTHERAPY OR IN COMBINATION WITH ANOTHER NON-BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUG (DMARD). FOR THOSE WITH A CONTRAINDICATION TO METHOTREXATE, DOCUMENTATION OF INADEQUATE RESPONSE OR INTOLERANCE TO AN ALTERNATE DMARD APPROPRIATE FOR THE TREATMENT OF RHEUMATOID ARTHRITIS IS REQUIRED. COVERED FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS. IN ADDITION, THE PATIENT MUST HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO METHOTREXATE OR ANOTHER DMARD. COVERED FOR THE DIAGNOSIS OF ULCERATIVE COLITIS IN PATIENTS WITH INADEQUATE RESPONE OR INTOLERANCE TO TWO CLASSES: THIOPURINE, 5-AMINOSALYICYLATE, CYCLOSPORINE, OR IV/ORAL STEROIDS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# XENAZINE

## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | FOR THE TREATMENT OF CARCINOID SYNDROME DIARRHEA, COVERAGE WILL NOT BE PROVIDED IN THE ABSENCE OF CONCURRENT SOMASTATIN ANALOG THERAPY (LANREOTIDE OR OCTREOTIDE). |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ONCOLOGIST, HEMATOLOGIST, ENDOCRINOLOGIST, OR GASTROENTEROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE TREATMENT OF CARCINOID SYNDROME DIARRHEA WITH DOCUMENTATION OF CONTINUED DIARRHEA DESPITE A MINIMUM 3-MONTH TRIAL OF SOMASTATIN ANALOG THERAPY (LANREOTIDE OR OCTREOTIDE). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# XGEVA

## Products Affected

- Xgeva

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | XGEVA WILL NOT BE APPROVED FOR USE IN COMBINATION WITH ORAL OR INJECTABLE BISPHOSPHONATES. |
| **Required Medical Information** | PATIENT PROGRESS NOTES AND DOCUMENTATION OF DIAGNOSIS. FOR A DIAGNOSIS OF BONE METASTASIS FROM SOLID TUMOR, PROVIDE RADIOGRAPHIC EVIDENCE (X-RAY, CT, OR MRI) OF A LEAST ONE BONE METASTASIS. |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ONCOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR THE PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA AND IN PATIENTS WITH BONE METASTASES FROM SOLID TUMORS FOR WHICH THERE IS RADIOGRAPHIC EVIDENCE OF AT LEAST ONE BONE METASTASIS. APPROVED FOR TREATMENT OF GIANT CELL TUMOR OF THE BONE (IN ADULTS AND SKELETALLY MATURE ADOLESCENTS) THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY. APPROVED FOR THE TREATMENT OF HYPERCALCEMIA OF MALIGNANCY REFRACTORY TO BISPHOSPHONATE THERAPY. |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | XOLAIR IS EXCLUDED IN PATIENTS WEIGHING OVER 150KG. ADMINISTRATION IN ANY SETTING OTHER THAN A HEALTHCARE SETTING IS EXCLUDED. XOLAIR WILL NOT BE COVERED FOR THE TREATMENT OF ATOPIC DERMATITIS. |
| **Required Medical Information** | FOR THE DIAGNOSIS OF ASTHMA: PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM THE DIAGNOSIS OF ASTHMA (SUCH AS RAST TESTING AND PULMONARY FUNCTION TESTS OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), AND DOCUMENTATION OF PREVIOUS THERAPIES. FOR THE DIAGNOSIS OF CHRONIC IDIOPATHIC URTICARIA: PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES. |
| **Age Restrictions** | FOR A DIAGNOSIS OF ASTHMA, PATIENT MUST BE 6 YEARS OF AGE OR OLDER. FOR THE DIAGNOSIS OF CHRONIC IDIOPATHIC URTICARIA, PATIENT MUST BE 12 YEARS OF AGE OR OLDER. |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ALLERGIST/IMMUNOLOGIST, PULMONOLOGIST, OR DERMATOLOGIST DEPENDING ON THE CONDITION BEING TREATED |
| **Coverage Duration** | INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER |
| **Other Criteria** | XOLAIR IS COVERED FOR THE TREATMENT OF MODERATE TO SEVERE PERSISTENT ASTHMA. THE PATIENT MUST BE MAINTAINED ON ASTHMA TREATMENT CONSISTENT WITH THE NHLBI GUIDELINES, WHICH RECOMMEND THE COMBINATION OF A HIGH DOSE INHALED STEROID WITH ONE OTHER CONTROLLER MEDICATION, SUCH AS A LONG-ACTING BETA AGONIST, LEUKOTRIENE INHIBITOR, OR THEOPHYLLINE. CONSIDERATION WILL BE GIVEN FOR PATIENTS WHO ARE UNABLE TO TOLERATE HIGH-DOSE INHALED STEROIDS OR |

| PA Criteria | Criteria Details |
| --- | --- |
| | HAVE A CONTRAINDICATION TO CONTROLLER MEDICATIONS INDICATED IN THE NHLBI GUIDELINES. FOR PATIENTS AGES 12 AND OLDER, PT MUST BE EXPERIENCING ASTHMA EXACERBATIONS AND THE PATIENT MUST HAVE BASELINE IGE LEVELS BETWEEN 30 AND 700 IU/ML. FOR PATIENTS AGES 6 AND LESS THAN 12, PT MUST BE EXPERIENCING ASTHMA EXACERBATIONS AND THE PATIENT MUST HAVE BASELINE IGE LEVELS BETWEEN 30 AND 1300 IU/ML. PATIENT MUST HAVE DOCUMENTED EVIDENCE OF AT LEAST 1 PERENNIAL AEROALLERGEN (EG, HOUSE DUST MITE [DERMATOPHAGOIDES FARINAE, D. PTERONYSSINUS], ANIMAL DANDER (DOG, CAT), COCKROACH, FEATHERS, MOLD SPORES) BY SKIN TEST OR IN VITRO TESTING. UPON RECERTIFICATION, DOCUMENTATION SHOULD BE PROVIDED VALIDATING REDUCTION IN ASTHMA EXACERBATIONS. XOLAIR IS COVERED FOR THE DIAGNOSIS OF CHRONIC IDIOPATHIC URTICARIA IN PATIENTS THAT HAVE EXPERIENCED AT LEAST A SIX-MONTH HISTORY OF URTICARIA AND THE PRESENCE OF HIVES ASSOCIATED WITH ITCHING. IN ADDITION, THE PATIENT MUST HAVE A DOCUMENTED HISTORY OF SYMPTOMATIC FAILURE OF H1 ANTIHISTAMINE TREATMENT. UPON RECERTIFICATION, DOCUMENTATION SHOULD BE PROVIDED VALIDATING RESPONSE TO THERAPY (SUCH AS DECREASED SEVERITY OF ITCHING, DECREASED SIZE OF HIVES, DECREASED NUMBER OF HIVES). REQUESTS WILL ALSO BE EVALUATED FOR PART B VS PART D COVERAGE AND OFF-LABEL USE. |

# XYREM

## Products Affected

- Xyrem

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | USE OF XYREM TO TREAT INSOMNIA IS EXCLUDED |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (NARCOLEPSY MUST BE DOCUMENTED IN A SLEEP STUDY), AND DOCUMENTATION OF PREVIOUS THERAPIES (WHEN USED FOR EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY, THE PATIENT MUST HAVE HAD AT LEAST A 4 WEEK TRIAL OF MODAFINIL (PROVIGIL). |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A NEUROLOGIST OR SLEEP SPECIALIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | XYREM IS COVERED FOR THE TREATMENT OF CATAPLEXY SECONDARY TO NARCOLEPSY. XYREM IS COVERED FOR EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY MEETING ALL OF THE FOLLOWING CRITERIA : NARCOLEPSY CONFIRMED BY SLEEP STUDY WHICH MUST BE PROVIDED AND PATIENT MUST BE FOLLOWED BY A QUALIFIED SPECIALIST AS LISTED IN THE PRESCRIBER RESTRICTIONS SECTION AND THE PATIENT MUST HAVE FAILED AT LEAST A 4 WEEK TRIAL OF MODAFINIL. |

# YONSA

## Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | AS LIMITED BY FDA-LABELING |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST. |
| **Age Restrictions** | PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY AN ONCOLOGIST OR UROLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | COVERED FOR A DIAGNOSIS OF CASTRATION-RESISTANT PROSTATE CANCER WITH RADIOGRAPHIC EVIDENCE OF PROGRESSIVE METASTATIC DISEASE. IN ADDITION, THE PATIENT MUST HAVE FAILED TO RESPOND TO, OR IS INTOLERANT TO ABIRATERONE OR ZYTIGA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ZAVESCA

## Products Affected

- miglustat
- Zavesca

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | COMBINATION THERAPY OF MIGLUSTAT (ZAVESCA) AND CEREZYME/CEREDASE IS EXCLUDED |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS ENZYME ANALYSIS, MUTATION ANALYSIS, OR BONE MARROW STUDIES, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS), AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | NONE |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | MIGLUSTAT (ZAVESCA) IS COVERED FOR TYPE 1 GAUCHER DISEASE IN PATIENTS FOR WHOM ENZYME REPLACEMENT THERAPY WITH CEREZYME IS NOT A THERAPEUTIC OPTION DUE ALLERGY, HYPERSENSITIVITY, OR POOR VENOUS ACCESS. |

# ZEPATIER

## Products Affected

- Zepatier

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | ZEPATIER WILL NOT BE COVERED IN COMBINATION WITH STRONG CYP3A INDUCERS, EFAVIRENZ, OR OATP1B1/3 INHITIBORS. ZEPATIER WILL NOT BE COVERED IN PATIENTS WITH MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). ZEPATIER WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA-APPROVED INDICATION, COMPENDIA, OR AASLD/IDSA GUIDELINES. |
| **Required Medical Information** | DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO INCLUDE BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE). |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST |
| **Coverage Duration** | 12 TO 16 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE) |
| **Other Criteria** | IF AASLD/IDSA GUIDELINES RECOMMENDS THE USE OF HARVONI OR MAVYRET OR EPCLUSA TO TREAT A GIVEN GENOTYPE, THEN PATIENT MUST HAVE DOCUMENTATION OF A SEVERE INTOLERANCE (THAT PREVENTS COMPLETION OF THERAPY) OR A CONTRAINDICATION TO HARVONI OR MAVYRET OR EPCLUSA. FOR OFF- LABEL REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE. |

# ZONTIVITY

## Products Affected

- Zontivity

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | HISTORY OF STROKE, TRANSIENT ISCHEMIC ATTACK, OR INTRACRANIAL HEMORRHAGE OR CURRENT ACTIVE PATHOLOGICAL BLEEDING (SUCH AS INTRACRANIAL HEMORRHAGE, PEPTIC ULCER BLEEDING). |
| **Required Medical Information** | PATIENT PROGRESS NOTES, DOCUMENTATION OF DIAGNOSIS AND HISTORY OF MYOCARDIAL INFARCTION AND/OR PERIPHERAL ARTERIAL DISEASE, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, AND DOCUMENTATION OF PREVIOUS THERAPIES |
| **Age Restrictions** | PATIENT MUST BE AT LEAST 18 YEARS OLD |
| **Prescriber Restrictions** | MUST BE PRESCRIBED BY A CARDIOLOGIST |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ZONTIVITY WILL NOT BE COVERED FOR THE REDUCTION OF CARDIOVASCULAR EVENTS IN PATIENTS WITH A HISTORY OF STROKE, TRANSIENT ISCHEMIC ATTACK, INTRACRANIAL HERMORRHAGE, OR ACTIVE PATHOLOGICAL BLEEDING (SUCH AS INTRACRANIAL OR PEPTIC ULCER BLEEDING). |

# ZOSTAVAX AGE EDIT

## Products Affected

- Zostavax (PF)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | EXCLUDED FOR INDIVIDUALS UNDER THE AGE OF 50 |
| **Required Medical Information** | DOCUMENTATION OF DIAGNOSIS |
| **Age Restrictions** | PA APPLIES FOR PATIENTS AGED 50 AND YOUNGER ONLY |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# ZURAMPIC

## Products Affected

- Zurampic

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D. |
| **Exclusion Criteria** | NONE |
| **Required Medical Information** | DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, CURRENT SERUM URIC ACID LEVEL |
| **Age Restrictions** | PATIENT MUST BE 18 YEARS OF AGE OR OLDER |
| **Prescriber Restrictions** | NONE |
| **Coverage Duration** | ONE YEAR |
| **Other Criteria** | ZURAMPIC IS COVERED FOR A DIAGNOSIS OF GOUT IN PATIENTS WITH SERUM URIC ACID LEVELS ABOVE 6.5MG/DL DESPITE CURRENT THERAPY WITH ALLOPURINOL (300MG DAILY OR 200MG DAILY IF RENAL IMPAIRMENT) OR FEBUXOSTAT (80MG DAILY). IN ADDITION, THE PATIENT MUST HAVE SIGNIFICANT INTOLERANCE, THERAPEUTIC FAILURE, OR CONTRAINDICATION (SUCH AS A SULFA ALLERGY) TO PROBENECID. ZURAMPIC MUST BE USED IN COMBINATION WITH EITHER ALLOPURINOL OR FEBUXOSTAT. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS. |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- acetylcysteine
- acyclovir sodium intravenous solution
- Admelog U-100 Insulin lispro
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 5 mg/mL
- AmBisome
- Aminosyn 7 % with electrolytes
- Aminosyn 8.5 %-electrolytes
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn II 8.5 %
- Aminosyn II 8.5 %-electrolytes
- Aminosyn-HBC 7%
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- Aminosyn-RF 5.2 %
- amphotericin B
- aprepitant oral capsule 125 mg, 40 mg, 80 mg
- aprepitant oral capsule,dose pack
- Astagraf XL
- Azasan
- azathioprine
- Bethkis
- Brovana
- budesonide inhalation
- CellCept
- Clinimix 5%/D15W Sulfite Free
- Clinimix 5%/D25W sulfite-free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 4.25%-D25W sulf-free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix E 2.75%/D10W Sul Free
- Clinimix E 2.75%/D5W Sulf Free
- Clinimix E 4.25%/D10W Sul Free
- Clinimix E 4.25%/D25W Sul Free
- Clinimix E 4.25%/D5W Sulf Free
- Clinimix E 5%/D15W Sulfit Free
- Clinimix E 5%/D20W Sulfit Free
- Clinisol SF 15 %
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine modified
- cyclosporine oral capsule
- dexamethasone oral elixir
- dexamethasone oral tablet
- Emend oral capsule 125 mg, 40 mg, 80 mg
- Emend oral capsule,dose pack
- Emend oral suspension for reconstitution
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF) intramuscular syringe
- Envarsus XR
- Freamine HBC 6.9 %
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- granisetron HCl oral
- Hepatamine 8%
- Humalog U-100 Insulin subcutaneous solution
- Humulin R Regular U-100 Insuln
- Humulin R U-500 (Conc) Insulin
- Imovax Rabies Vaccine (PF)
- Intralipid intravenous emulsion 20 %, 30 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol HCl
- Medrol oral tablet 2 mg
- methotrexate sodium
- methotrexate sodium (PF) injection solution
- methylprednisolone oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- Myfortic
- Nebupent
- Neoral
- Nephramine 5.4 %
- Nutrilipid
- ondansetron
- ondansetron HCl oral solution

- ondansetron HCl oral tablet 24 mg, 4 mg, 8 mg
- Perforomist
- prednisolone oral solution 15 mg/5 mL
- prednisolone sodium phosphate oral solution 10 mg/5 mL, 20 mg/5 mL (4 mg/mL), 25 mg/5 mL (5 mg/mL), 5 mg base/5 mL (6.7 mg/5 mL)
- Prednisone Intensol
- prednisone oral solution
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Procalamine 3%
- Prograf oral
- Prosol 20 %
- Pulmicort
- RabAvert (PF)
- Rapamune
- Rayos
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral
- sirolimus oral tablet
- tacrolimus oral
- Tobi
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- trimethobenzamide oral
- TrophAmine 10 %
- Trophamine 6%
- Varubi oral
- Xatmep
- Xopenex
- Xopenex Concentrate
- Zortress
- Zuplenz

## Details

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

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