Prior Authorization Requirements
Effective January 1, 2020

ABILIFY MYCITE

Products Affected

- Abilify MyCite

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	INITIAL APPROVAL 3 MOS. RECERT EVERY 1 YR THEREAFTER
Other Criteria	COVERED FOR A DIAGNOSIS OF SCHIZOPHRENIA, BIPOLAR I DISORDER, OR MAJOR DEPRESSIVE DISORDER IN PATIENTS WHO HAVE HAD SEVERE INTOLERANCE OR DRUG FAILURE WITH GENERIC ARIPIPRAZOLE TABLETS AND LONG-ACTING INJECTABLE ARIPIPRAZOLE (ABILIFY MAINTENA). RECERTIFICATION WILL REQUIRE DOCUMENTATION THAT THIS PRODUCT HAS ALLOWED AN IMPROVEMENT IN RESPONSE TO TREATMENT. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACTEMRA

Products Affected

- Actemra ACTPen
- Actemra subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS FOR RA, JIA, AND GIANT CELL ARTERITIS. 6 MONTHS FOR USE WITH CAR-T CELL THERAPY
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACTHAR

Products Affected

- Acthar

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY 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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ACTIMMUNE

Products Affected

- Actimmune

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ADEMPAS

Products Affected

- Adempas

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	FOR PULMONARY HYPERTENSION: RESULTS OF A RIGHT HEART CATHETERIZATION, CURRENT AND PREVIOUS THERAPIES FOR THIS DIAGNOSIS. FOR CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH): DOCUMENTATION OF DIAGNOSIS AND SURGICAL HISTORY (IF APPLICABLE).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION DIAGNOSED BY RIGHT HEART CATHETERIZATION SHOWING A MEAN ARTERY PRESSURE OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST. THERE MUST ALSO BE DOCUMENTATON OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GENERIC SILDENAFIL OR TADALAFIL/ALYQ AND ONE OTHER AGENT WITH A DIFFERENT MECHANISM OF ACTION, SUCH AS A PROSTACYCLIN OR AN ENDOTHELIN RECEPTOR ANTAGONIST. COVERED FOR THE TREATMENT OF CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHEN THE PATIENT HAS DOCUMENTATION OF RECURRENT OR PERSISTANT DISEASE AFTER SURGICAL TREATMENT OR DOCUMENTATION OF INOPERABLE DISEASE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED

PA Criteria	Criteria Details
	ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS AAT SERUM LEVELS, GENOTYPE TESTING, AND PULMONARY FUNCTION TESTING, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS, AND DOCUMENTATION OF PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST
Coverage Duration	ONE YEAR, ONLY AS WEEKLY INFUSIONS
Other Criteria	COVERAGE WILL NOT 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 EMPHYSEMA DUE TO AAT DEFICIENCY MUST BE MAINTAINED ON REGIMENS SIMILAR TO THOSE PATIENTS WITH

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AMPHETAMINE

Products Affected

- amphetamine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED WHEN USED FOR WEIGHT LOSS, EVEN IF NON-COSMETIC (SUCH AS MORBID OBESITY)
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ARIKAYCE

Products Affected

- Arikayce

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED WHEN USED FOR THE TREATMENT OF PATIENTS WITH NON-REFRACTORY MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE OR WHEN BEING USED AS A SINGLE AGENT.
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES, PERTINENT LAB/DIAGNOSTIC TEST RESULTS. FOR THE DIAGNOSIS OF REFRACTORY MYCOBACTERIUM AVIUM COMPLEX DISEASE, SPUTUM CULTURE RESULTS ARE REQUIRED.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN INFECTIOUS DISEASE SPECIALIST OR PULMONOLOGIST
Coverage Duration	INITIAL APPROVAL 6 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ARMODAFINIL

Products Affected

- armodafinil

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR SLEEP SPECIALIST FOR A DIAGNOSIS OF 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	ARMODAFINIL 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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AURYXIA

Products Affected

- Auryxia

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR A DIAGNOSIS OF IRON DEFICIENCY ANEMIA, AS IRON PRODUCTS ARE EXCLUDED FROM PART D COVERAGE.
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

AUSTEDO

Products Affected

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

PA Criteria	Criteria Details
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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR A PSYCHIATRIST
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BENLYSTA

Products Affected

- Benlysta subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR PATIENTS WHO ARE CURRENTLY RECEIVING TREATMENT WITH ANY B-CELL-TARGETED THERAPY OR BIOLOGIC
Required Medical Information	DIAGNOSIS, 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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
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). REQUESTS WILL ALSO BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

BERINERT

Products Affected

- Berinert intravenous kit

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR THE PROPHYLAXIS OF 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 ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III FOR THE TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACKS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CABLIVI

Products Affected

- Cablivi injection kit

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES 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 HEMATOLOGIST
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CARBAGLU

Products Affected

- Carbaglu

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	PATIENT MUST HAVE A DIAGNOSIS OF ACUTE OR CHRONIC HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CERDELGA

Products Affected

- Cerdelga

PA Criteria	Criteria Details
Exclusion Criteria	COMBINATION THERAPY WITH CERDELGA AND ENZYME REPLACEMENT THERAPY (SUCH AS ELEYSO, CEREZYME) IS EXCLUDED. CONCOMITANT USE OF A MODERATE OR STRONG CYP2D6 INHIBITOR WITH A MODERATE OR STRONG CYP3A INHIBITOR IN EXTENSIVE METABOLIZERS OR INTERMEDIATE METABOLIZERS IS EXCLUDED. CONCOMITANT USE OF A STRONG CYP3A INHIBITOR IN POOR METABOLIZERS OR INTERMEDIATE METABOLIZERS IS EXCLUDED. CERDELGA IS EXCLUDED IN PATIENTS WITH PRE-EXISTING CARDIAC DISEASE, LONG Q-T SYNDROME, AND FOR THOSE WHO TAKE CLASS 1A OR CLASS III ANTIARRHYTHMIC.
Required Medical Information	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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	CERDELGA IS COVERED FOR TYPE 1 GAUCHER DISEASE IN PATIENTS WHO ARE CYP2D6 EXTENSIVE METABOLIZERS, INTERMEDIATE METABOLIZERS OR POOR METABOLIZERS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CESAMET

Products Affected

- Cesamet

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CGRP ANTAGONISTS

Products Affected

- Aimovig Autoinjector
- Ajovy
- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CGRP CLUSTER HEADACHE

Products Affected

- Emgality Syringe subcutaneous syringe 300 mg/3 mL (100 mg/mL x 3)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
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	6 MONTHS
Other Criteria	COVERED FOR THE DIAGNOSIS OF EPISODIC CLUSTER HEADACHES, DEFINED BY THE INTERNATIONAL CLASSIFICATION OF HEADACHE DISORDERS (ICHD) AS CLUSTER PERIODS LASTING FROM SEVEN DAYS TO ONE YEAR. A CLUSTER PERIOD THAT EXCEEDS ONE YEAR WILL BE CONSIDERED A CHRONIC, RATHER THAN EPISODIC, CLUSTER HEADACHE DIAGNOSIS. 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 EPISODIC CLUSTER HEADACHE (SUCH AS VERAPAMIL AND LITHIUM), 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 RECERTIFICATION, PRESCRIBER MUST ATTEST TO THE CLINICAL RESPONSE TO TREATMENT DEFINED AS A DECREASE IN THE FREQUENCY OF CLUSTER HEADACHE ATTACKS. AT THE TIME OF RECERTIFICATION, THE PATIENT MUST ALSO STILL BE IN AN ACTIVE CLUSTER PERIOD. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED

PA Criteria	Criteria Details
	ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CHOLBAM

Products Affected

- Cholbam

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS GAS CHROMATOGRAPHY-MASS SPECTROMETRY URINE ANALYSIS, LIVER FUNCTION TESTS AND OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST, GASTROENTEROLOGIST, GENETICIST, HEPATOLOGIST, OR METABOLIC SPECIALIST.
Coverage Duration	INITIAL APPROVAL 3 MONTHS. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CIMZIA

Products Affected

- Cimzia
- Cimzia Powder for Reconst

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
Other Criteria	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 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

PA Criteria	Criteria Details
	DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

CINRYZE

Products Affected

- Cinryze

PA Criteria	Criteria Details
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 ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III. PROPHYLACTIC THERAPY WILL BE COVERED 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COPAXONE 20MG

Products Affected

- Copaxone subcutaneous syringe 20 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

COSENTYX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A DERMATOLOGIST OR RHEUMATOLOGIST
Coverage Duration	TWO YEARS
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 ARTHRITIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS

PA Criteria	Criteria Details
	WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DICLOFENAC 3% TOPICAL GEL

Products Affected

- diclofenac sodium topical gel 3 %

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	DICLOFENAC 3% GEL WILL BE COVERED FOR THE DIAGNOSIS OF ACTINIC KERATOSES. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DICLOFENAC PATCH

Products Affected

- diclofenac epolamine

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	THREE MONTHS
Other Criteria	DICLOFENAC PATCH WILL BE COVERED FOR THE TREATMENT OF ACUTE PAIN DUE TO MINOR STRAINS, SPRAINS, AND CONTUSIONS. ACUTE PAIN IS DEFINED AS SHORT-TERM PAIN NOT LASTING LONGER THAN A THREE MONTH PERIOD. CHRONIC PAIN IS DEFINED AS A CONDITION THAT REQUIRES PAIN MANAGEMENT THAT EXCEEDS A THREE MONTH PERIOD, SUCH AS RHEUMATOID ARTHRITIS, OSTEOARTHRITIS AND PERIPHERAL NEUROPATHY.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DOPTELET

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A HEMATOLOGIST, GASTROENTEROLOGIST, OR HEPATOLOGIST
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DOXEPIN TOPICAL CREAM

Products Affected

- doxepin topical

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	DOXEPIN TOPICAL CREAM WILL BE COVERED FOR THE TREATMENT OF SHORT-TERM MANAGEMENT OF MODERATE PRURITUS IN ADULTS WITH ATOPIC DERMATITIS OR LICHEN SIMPLEX CHRONICUS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

DUPIXENT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TESTS USED TO CONFIRM DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EMFLAZA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, RESULTS OF DUCHENNE MUSCULAR DYSTROPHY (DMD) GENE MUTATION STUDY
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR ALL FDA-APPROVED INDICATIONS WITH REQUIRED DOCUMENTATION OF SIGNIFICANT SIDE EFFECTS RESULTING FROM A MINIMUM 3-MONTH TRIAL OF ORAL PREDNISONE. EXAMPLES OF SIGNIFICANT PREDNISONE SIDE EFFECTS INCLUDE CUSHINGOID APPEARANCE, CENTRAL (TRUNCAL) OBESITY, UNDESIRABLE WEIGHT GAIN, INABILITY TO MANAGE DIABETES OR HYPERTENSION, STEROID-INDUCED MANIA, OR SEPSIS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
Other Criteria	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 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

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ENDARI

Products Affected

- Endari

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A HEMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR SYMPTOMATIC PAIN RELIEF OF SICKLE CELL DISEASE. IN ADDITION, PATIENT MUST HAVE EXPERIENCED INADEQUATE PAIN RELIEF WITH A MINIMUM THREE-MONTH TRIAL OR A HEMATOLOGIC TOXICITY REACTION WITH HYDROXYUREA 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EPCLUSA

Products Affected

- Epclusa
- sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	EPCLUSA OR SOFOSBUVIR/VELPATASVIR 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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST
Coverage Duration	TWO YEARS
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ESBRIET

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	ESBRIET WILL BE COVERED FOR A DOCUMENTED DIAGNOSIS OF IDIOPATHIC PULMONARY FIBROSIS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, DIALYSIS STATUS (ONLY IF DIAGNOSIS OF END-STATE RENAL DISEASE)
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	FOR A DIAGNOSIS OF END STAGE RENAL DISEASE ON DIALYSIS, CMS EXPECTS THAT THIS DRUG SHOULD ROUTINELY BE PROVIDED BY A DIALYSIS CENTER AND BILLED TO MEDICARE PART B AS PART OF A BUNDLED PAYMENT ARRANGEMENT (IF APPLICABLE). ALL OTHER DIAGNOSES UNRELATED TO END STAGE RENAL DISEASE ON DIALYSIS WOULD BE EVALUATED FOR COVERAGE UNDER THE PART D BENEFIT.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

EVENITY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR (REFER TO OTHER CRITERIA SECTION)
Other Criteria	COVERED FOR POST-MENOPAUSAL WOMEN AT HIGH RISK FOR FRACTURE. THE PATIENT MUST BE CONSIDERED HIGH RISK FOR FRACTURE, WHICH IS DEFINED AS 1) HISTORY OF PREVIOUS OSTEOPOROSIS-RELATED FRACTURE, 2) T- SCORE OF -2.5 SD OR LESS, 3) T-SCORE BETWEEN -1.0 AND -2.5 SD BELOW NORMAL AND A FRAX SCORE FOR HIP FRACTURE OF 3% OR GREATER OR THE RISK FOR OTHER BONE FRACTURE IS 20% OR GREATER. PATIENT MUST ALSO HAVE EXPERIENCED THERAPEUTIC FAILURE, SEVERE INTOLERANCE OR A CONTRAINDICATION TO AN ORAL BISPHOSPHONATE OR BE AN INAPPROPRIATE CANDIDATE FOR ORAL BISPHOSPHONATE THERAPY BASED ON CLINICAL PRESENTATION. THERAPEUTIC FAILURE IS DEFINED AS A DECREASE IN BONE MINERAL DENSITY OR A FRACTURE WHILE ON 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

PA Criteria	Criteria Details
	BEDRIDDEN/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 DURATION TO EXCEED MORE THAN 12 MONTHLY DOSES. REQUEST WILL ALSO BE EVALUATED FOR PART B VERSUS PART D COVERAGE. REQUESTS FOR NON-FDA CMS Review -accepted Indications.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FANAPT/LATUDA/SAPHRIS

Products Affected

- Fanapt
- Latuda
- Saphris

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FASENRA

Products Affected

- Fasenra

PA Criteria	Criteria Details
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 THAN 90% OF THE PREDICTED VALUE OR A RATIO OF THE FEV1 TO THE FORCED VITAL CAPACITY (FVC) OF LESS THAN 0.8. THE

PA Criteria	Criteria Details
	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 2 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FIRAZYR

Products Affected

- Firazyr
- icatibant

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR THE PROPHYLAXIS OF 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 ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III FOR THE TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACKS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FIRDAPSE

Products Affected

- Firdapse

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR NEUROMUSCULAR SPECIALIST
Coverage Duration	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

FORTEO

Products Affected

- Forteo

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS (REFER TO OTHER CRITERIA SECTION)
Other Criteria	PATIENT MUST FALL INTO ONE OF THE FOLLOWING CATEGORIES: POSTMENOPAUSAL WOMAN, PRIMARY OR 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 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

PA Criteria	Criteria Details
	BISPHOSPHONATES MAY BE CLINICALLY INAPPROPRIATE FOR A PATIENT THAT IS BED-RIDDEN/UNABLE TO SIT UPRIGHT FOR 30 MINUTES UNSUPERVISED OR HAS ESOPHAGEAL ULCERATIONS, ESOPHAGEAL STRICTURE, BARRETT'S ESOPHAGITIS, OR ACTIVE ULCERS. IN ADDITION, REQUESTS FOR FORTEO FOR A DIAGNOSIS OF POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AT HIGH RISK FOR FRACTURE WILL REQUIRE DOCUMENTATION OF SEVERE INTOLERANCE OR A CONTRAINDICATION TO TYMLOS. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GALAFOLD

Products Affected

- Galafold

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED IN COMBINATION WITH FABRAZYME (AGALSIDASE BETA). EXCLUDED FOR PATIENTS WITH A GLOMERULAR FILTRATION RATE (GFR) LESS THAN 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), ACROPARESTHESIA (NEUROPATHIC PAIN IN THE HANDS AND FEET), CORNEA VERTICILLATA AND CHARACTERISTIC

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GATTEX

Products Affected

- Gattex 30-Vial

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GOCOVRI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	6 MONTHS FOR ENDOMETRIOSIS. ONE YEAR FOR ALL OTHER DIAGNOSES.
Other Criteria	LUPRON/LEUPROLIDE IS COVERED FOR MANAGEMENT OF ENDOMETRIOSIS, INCLUDING PAIN RELIEF AND REDUCTION OF ENDOMETRIOTIC LESIONS. AUTHORIZATION WILL BE FOR UP TO 6 MONTHS, BECAUSE OF A LACK OF SAFETY DATA WITH LONG TERM USE, AND CONCERNS REGARDING EFFECTS ON BONE DENSITY. LUPRON/LEUPROLIDE IS COVERED FOR TREATMENT OF ADVANCED 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 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.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

GRALISE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY 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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
Exclusion Criteria	WHEN USED TO INCREASE HEIGHT, GROWTH HORMONE THERAPY WILL NOT BE COVERED IN PEDIATRIC PATIENTS WITH CLOSED EPIPHYSES.
Required Medical Information	GENERAL-GROWTH CHARTS, HEIGHT/WEIGHT, HEIGHT VELOCITY. SOMATOTROPIN DEFICIENCY IN CHILDREN REQUIRES DOCUMENTATION OF DIMINISHED GROWTH HORMONE RESPONSE (MAX PEAK LESS THAN 10NG/ML) TO 2 OR MORE DIFFERENT PROVOCATION TESTS (SUCH AS LEVODOPA, INSULIN-INDUCED HYPOGLYCEMIA, ARGININE, CLONIDINE, OR GLUCAGON) OR DOCUMENTATION OF LOW IGF-1 OR IGFBP3 FOR AGE, SEX, AND PUBERTAL STATUS IN CHILDREN AGE 6 OR GREATER IN THE ABSENCE OF CHRONIC DISEASE ALONG WITH A HEIGHT VELOCITY LESS THAN 25TH PERCENTILE IN THE 6-12 MONTHS PRIOR TO GROWTH HORMONE THERAPY. IN ADDITION TO ONE OF THE ABOVE FINDINGS THERE MUST ALSO BE DOCUMENTATION OF TWO OF THE FOLLOWING: 1) GROWTH VELOCITY LESS THAN 7CM/YR BEFORE AGE THREE 2) BONE AGE AT LEAST 2 SD BELOW NORMAL FOR CHRONOLOGICAL AGE 3) A KNOWN RISK FACTOR FOR GROWTH HORMONE DEFICIENCY (SUCH AS CONGENITAL HYPOPITUITARISM, PANHYPOPITUITARISM, OR PRIOR BRAIN RADIATION). SOMATOTROPIN DEFICIENCY IN ADULTS REQUIRES DOCUMENTATION OF NEGATIVE RESPONSE TO PROVOCATIVE TEST WITH MAX PEAK OF 5NG/ML ALONG WITH DOCUMENTATION OF CLINICAL SYMPTOMS SUCH AS INCREASED WEIGHT AND BODY FAT MASS, DECREASED LEAN BODY MASS, DECREASED EXERCISE TOLERANCE, DECREASED MUSCLE MASS AND STRENGTH, REDUCED CARDIAC PERFORMANCE, REDUCED BONE DENSITY, POOR SLEEP, IMPAIRED SENSE OF WELL-BEING OR LACK OF MOTIVATION. ALTERNATIVELY, WILL ACCEPT INSULIN TOLERANCE TEST

PA Criteria	Criteria Details
	WITH MAX PEAK LESS THAN 5NG/ML (UNLESS CONTRAINDICATED IN WHICH CASE WILL ACCEPT IV ARGININE IN COMBINATION WITH GH-RELEASING HORMONE WITH MAX PEAK LESS THAN 10NG/ML.) IF THERE IS DOCUMENTATION OF DEFICIENCY OF 3 OR MORE PITUITARY HORMONES, ITT OR ARGININE TESTS ARE NOT REQUIRED. RECERTIFICATION- IN CHILDREN REQUIRES THE FOLLOWING EVERY 12 MONTHS: CURRENT GROWTH VELOCITY, GROWTH CHARTS (HEIGHT AND WEIGHT), CURRENT BONE AGE, PUBERTY STATUS, AND RADIOGRAPHIC TESTING TO DETERMINE IF EPIPHYSES ARE CLOSED AT AGE 14 IN GIRLS AND AGE 16 IN BOYS.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST, PEDIATRIC ENDOCRINOLOGIST, NEPHROLOGIST, INFECTIOUS DISEASE SPECIALIST, OR GASTROENTEROLOGIST
Coverage Duration	ONE YEAR
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 abel UsesXE "Oxervate"□□ EMENT "Abstral"□□ fentanyl citrateXE 2 YEARS OF AGE. COVERED FOR NOONAN SYNDROME WITH SHORT STATURE (WHEN HEIGHT IS AT LEAST 2 SD BELOW NORMAL. COVERED FOR CHILDREN WITH SHOX DEFICIENCY DEMONSTRATED BY CHROMOSOME ANALYSIS AND WHOSE EPIPHYSES ARE NOT CLOSED. ADULTS AND CHILDREN-GROWTH HORMONE THERAPY IS COVERED FOR A DIAGNOSIS OF SOMATOTROPIN DEFICIENCY (SEE REQUIRED MEDICAL INFO). COVERED FOR AIDS WASTING OR CACHEXIA OR CHILDREN WITH HIV ASSOCIATED FAILURE TO THRIVE DEFINED AS A GREATER THAN 10% OF BASELINE WEIGHT LOSS OR WEIGHT LESS THAN 90% OF IDEAL BODY WEIGHT AND

PA Criteria	Criteria Details
	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HAEGARDA

Products Affected

- Haegarda

PA Criteria	Criteria Details
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 ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III. PROPHYLACTIC THERAPY WILL BE COVERED 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HARVONI

Products Affected

- Harvoni
- ledipasvir-sofosbuvir

PA Criteria	Criteria Details
Exclusion Criteria	HARVONI OR LEDIPASVIR/SOFOSBUVIR WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES.
Required Medical Information	DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	8 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE)
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HETLIOZ

Products Affected

- Hetlioz

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A SLEEP SPECIALIST OR NEUROLOGIST.
Coverage Duration	ONE YEAR
Other Criteria	HETLIOZ 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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

HORIZANT

Products Affected

- Horizant oral tablet extended release 300 mg, 600 mg

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY 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	FOR THE TREATMENT OF POST-HERPETIC NEURALGIA, THERE MUST BE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF GENERIC GABAPENTIN. FOR THE TREATMENT OF RESTLESS LEGS SYNDROME, THERE MUST BE DOCUMENTATION OF SEVERE INTOLERANCE OR CLINICAL FAILURE OF IMMEDIATE-RELEASE ROPINIROLE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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 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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
Other Criteria	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 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ILUMYA

Products Affected

- Ilumya

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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, SKYRIZI, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INBRIJA

Products Affected

- Inbrija inhalation capsule, w/inhalation device

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR PATIENTS WITH A DIAGNOSIS OF PARKINSON'S DISEASE WHO EXPERIENCE "WEARING OFF SYMPTOMS" WITH A CURRENT CARBIDOPA/LEVODOPA REGIMEN CONTAINING AT LEAST 100MG OF CARBIDOPA. IN ADDITION, PATIENT MUST HAVE ATTEMPTED TO IMPROVE "WEARING OFF SYMPTOMS" WITH A TRIAL OF BOTH 1) INCREASE IN THE DOSE OF THE ORAL CARBIDOPA/LEVODOPA REGIMEN AND 2) INCREASE IN THE FREQUENCY OF THE ORAL CARBIDOPA/LEVODOPA REGIMEN. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INCRELEX

Products Affected

- Increlex

PA Criteria	Criteria Details
Exclusion Criteria	INCRELEX WILL NOT BE COVERED FOR GROWTH PROMOTION IN PATIENTS WITH CLOSED EPIPHYSES OR AS A SUBSTITUTE FOR GROWTH HORMONE REPLACEMENT THERAPY. IV ADMINISTRATION WILL NOT BE COVERED
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS IGF-1 LEVELS AND GH LEVELS), 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INGREZZA

Products Affected

- Ingrezza Initiation Pack
- Ingrezza oral capsule 40 mg, 80 mg

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR PSYCHIATRIST
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

INJECTABLE ONCOLOGY

Products Affected

- Sylatron
- Synribo

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

IVIG

Products Affected

- 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
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS FOR CHRONIC CONDITIONS. ONE MONTH FOR ACUTE CONDITIONS. 5 DAYS FOR GUILLAIN-BARRE
Other Criteria	REQUESTS WILL BE EVALUATED FOR PART B VS PART D COVERAGE. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

JUBLIA

Products Affected

- Jublia

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS KOH STAIN OR CULTURE RESULTS), 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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

JUXTAPID

Products Affected

- Juxtapid

PA Criteria	Criteria Details
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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST
Coverage Duration	INITIAL 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

JYNARQUE

Products Affected

- Jynarque oral tablet
- Jynarque oral tablets, sequential

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEPHROLOGIST
Coverage Duration	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KALYDECO

Products Affected

- Kalydeco

PA Criteria	Criteria Details
Exclusion Criteria	COVERAGE WILL BE EXCLUDED IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508 DEL MUTATION IN THE CFTR GENE.
Required Medical Information	DIAGNOSIS, LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING FOR CFTR GENE MUTATION THAT IS RESPONSIVE TO IVACAFTOR
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KERYDIN

Products Affected

- Kerydin

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS KOH STAIN OR CULTURE RESULTS), 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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KEVEYIS

Products Affected

- Keveyis

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NEUROLOGIST OR GENETICIST
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KEVZARA

Products Affected

- Kevzara subcutaneous syringe

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS FOR RA. ONE YEAR FOR NOMID.
Other Criteria	COVERED FOR THE TREATMENT OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS FOR PATIENTS WITH DOCUMENTED FAILURE TO TWO OF THE FOLLOWING ALTERNATIVES: ENBREL, HUMIRA, ORENCIA, 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KORLYM

Products Affected

- Korlym

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED IN PATIENTS WHO ARE PREGNANT, WHO HAVE A HISTORY OF UNEXPLAINED VAGINAL BLEEDING/ENDOMETRIAL CHANGES, WHO ARE CURRENTLY RECEIVING 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	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS HBA1C LEVELS AND NEGATIVE PREGNANCY TEST IN WOMEN OF CHILDBEARING AGE), AND DOCUMENTATION OF PREVIOUS THERAPIES (FAILURE OF SURGERY OR NOT A CANDIDATE FOR SURGERY).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED IN PATIENTS WITH A DIAGNOSIS OF ENDOGENOUS 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 REQUIRE THE SUBMISSION OF PATIENT PROGRESS NOTES AND LAB WORK THAT DEMONSTRATES CLINICAL RESPONSE OR

PA Criteria	Criteria Details
	STABILIZATION OF DISEASE. INDIVIDUALS MUST MAINTAIN A HEMOGLOBIN A1C THAT IS EQUAL TO OR LESS THAN BASELINE FOR CONTINUED APPROVAL.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

KUVAN

Products Affected

- Kuvan

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

LIDOCAINE PATCH

Products Affected

- lidocaine topical adhesive patch,medicated
- ZTlido

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MARINOL

Products Affected

- dronabinol

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, AND DOCUMENTATION OF ANY PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ANOREXIA DUE TO AIDS-1 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MAVYRET

Products Affected

- Mavyret

PA Criteria	Criteria Details
Exclusion Criteria	MAVYRET WILL NOT BE COVERED IN PATIENTS WITH MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). MAYVRET WILL NOT BE COVERED FOR GENOTYPES THAT ARE NOT SUPPORTED BY ITS FDA APPROVED INDICATION, COMPENDIA, OR AASLD GUIDELINES.
Required Medical Information	DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS INCLUDING BASELINE HCV RNA RESULTS AND HCV GENOTYPE, AND DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES (IF APPLICABLE).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	8-16 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE)
Other Criteria	FOR OFF- LABEL MAVYRET REVIEWS, CRITERIA WILL BE APPLIED CONSISTENT WITH COMPENDIA AND CURRENT AASLD/IDSA GUIDANCE.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

METFORMIN ER

Products Affected

- metformin oral tablet,ER gast.retention 24 hr

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

METHAMPHETAMINE

Products Affected

- methamphetamine

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED WHEN USED FOR WEIGHT LOSS, EVEN IF NON-COSMETIC (SUCH AS MORBID OBESITY)
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MIGLUSTAT

Products Affected

- miglustat

PA Criteria	Criteria Details
Exclusion Criteria	COMBINATION THERAPY OF MIGLUSTAT (ZAVESCA) AND CEREZYME/CEREDASE IS EXCLUDED
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS ENZYME ANALYSIS, MUTATION ANALYSIS, BONE MARROW STUDIES, OR OTHER TESTS PERFORMED TO CONFIRM THE DIAGNOSIS)
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	MIGLUSTAT IS COVERED FOR TYPE 1 GAUCHER DISEASE IN PATIENTS FOR WHOM ENZYME REPLACEMENT THERAPY WITH CEREZYME IS NOT A THERAPEUTIC OPTION DUE ALLERGY, HYPERSENSITIVITY, OR POOR VENOUS ACCESS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MODAFINIL

Products Affected

- modafinil

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR SLEEP SPECIALIST FOR A DIAGNOSIS OF 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	MODAFINIL 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, MODAFINIL WILL BE COVERED WHEN THE PATIENT HAS TRIED AT LEAST 2 DIFFERENT ANTIDEPRESSANTS. FOR THE DRUGDEX COMPENDIA-SUPPORTED INDICATION OF ADHD, MODAFINIL WILL BE COVERED IN PATIENTS WHO HAVE HAD SEVERE INTOLERANCE OR THERAPEUTIC FAILURE TO TWO DIFFERENT MEDICATIONS APPROVED FOR THE TREATMENT OF ATTENTION DEFICIT DISORDER, SUCH AS METHYLPHENIDATE, AMPHETAMINE SALT, OR ATOMOXETINE.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MULPLETA

Products Affected

- Mulpleta

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS. WHILE NO SPECIFIC LAB/DIAGNOSTIC TESTS REQUIRED, PROVIDING THE RESULTS USED TO DIAGNOSE THE CONDITION IS RECOMMENDED, THEREBY REDUCING THE LIKELIHOOD THAT ADDITIONAL INFORMATION WILL BE NEEDED TO PROCESS THE REQUEST.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A HEMATOLOGIST, GASTROENTEROLOGIST, 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MULTIPLE SCLEROSIS

Products Affected

- Betaseron subcutaneous kit
- Extavia subcutaneous kit

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
Exclusion Criteria	USE OF MYALEPT IS EXCLUDED FOR THE FOLLOWING CONDITIONS: METABOLIC DISEASE NOT ASSOCIATED WITH CONGENITAL LEPTIN DEFICIENCY, HIV-ASSOCIATED LIPODYSTROPHY
Required Medical Information	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	COVERED FOR THE TREATMENT OF LEPTIN DEFICIENCY IN PATIENTS WITH CONGENITAL OR ACQUIRED GENERALIZED LIPODYSTROPHY. DIAGNOSIS IS CONFIRMED THROUGH LOW SERUM LEPTIN LEVELS AND THE ABSENCE OF SUBCUTANEOUS FAT.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

MYTESI

Products Affected

- Mytesi

PA Criteria	Criteria Details
Exclusion Criteria	DRUG THERAPY WILL NOT BE AUTHORIZED FOR INDIVIDUALS WHO HAVE A HISTORY OF ULCERATIVE COLITIS, 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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR THE SYMPTOMATIC RELIEF OF NONINFECTIOUS DIARRHEA IN INDIVIDUALS WITH HIV/AIDS ON ANTI-RETROVIRAL THERAPY. IN ADDITION, DOCUMENTATION OF CLINICAL FAILURE TO EITHER LOPERAMIDE OR DIPHENOXYLATE IS REQUIRED. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NAMZARIC

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	NAMZARIC WILL BE AUTHORIZED FOR PATIENTS WITH A DIAGNOSIS OF MODERATE TO SEVERE ALZHEIMER DISEASE. THERE MUST ALSO BE DOCUMENTED STABILIZATION ON DONEPEZIL FOR A MINIMUM OF THREE MONTHS IMMEDIATELY PRECEDING THE REQUEST FOR NAMZARIC. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, LABORATORY VALUES AS INDICATED UNDER OTHER COVERAGE, 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NITYR

Products Affected

- Nityr

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT THERAPIES, PERTINENT LAB/DIAGNOSTIC TEST RESULTS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN THE TREATMENT OF TYROSINEMIA TYPE 1 (SUCH AS A METABOLIC DISEASE SPECIALIST)
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR PATIENTS WITH A DIAGNOSIS OF HEREDITARY TYROSINEMIA TYPE 1. PATIENT MUST HAVE THE PRESENCE OF SUCCINYACETONE (SSA) IN THE URINE OR BLOOD / DRIED BLOOD SPOTS. PATIENT MUST HAVE CLINICAL FEATURES OF TYROSINEMIA TYPE 1, SUCH AS: FAILURE TO THRIVE, EMESIS, MELENA, HEPATOSPLENOMEGALY, LIVER DISEASE, CIRRHOSIS, CLOTTING ABNORMALITIES, RENAL DISEASE/FANCONI SYNDROME, NEUROLOGICAL CRISIS, RICKETS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NORTHERA

Products Affected

- Northera

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, 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	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	FOR ASTHMA WITH EOSINOPHILIC PHENOTYPE, MUST BE PRESCRIBED BY AN ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST. FOR EGPA, MUST BE PRESCRIBED BY AN ALLERGIST,IMMUNOLOGIST, PULMONOLOGIST, NEUROLOGIST, OR RHEUMATOLOGIST.
Coverage Duration	INITIAL APPROVAL 6 MOS. RECERT EVERY 1 YR THEREAFTER
Other Criteria	COVERED FOR THE TX OF SEV PERSISTENT ASTHMA WITH EOSINOPHILIC PHENOTYPE. PATIENT MUST HAVE A PERIPHERAL BLOOD EOSINOPHIL COUNT OF AT LEAST 150 CELLS/MCL WITHIN PAST 6 WKS BEFORE NUCALA REQ OR AT LEAST 300 CELLS/MCL 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 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

PA Criteria	Criteria Details
	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 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

PA Criteria	Criteria Details
	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUEDEXTA

Products Affected

- Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS WILL ALSO BE EVALUATED FOR OFF-LABEL USE.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUPLAZID

Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg

PA Criteria	Criteria Details
Exclusion Criteria	PER THE BLACK BOX WARNING ON NUPLAZID, ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. THEREFORE, NUPLAZID WILL NOT BE COVERED FOR ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.
Required Medical Information	DIAGNOSIS, DIAGNOSTIC TEST RESULTS, CURRENT AND PREVIOUS THERAPIES FOR THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST, PSYCHIATRIST, OR GERIATRICIAN
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

NUZYRA

Products Affected

- Nuzyra (7 Day with Load Dose)
- Nuzyra (7 Day)
- Nuzyra oral

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	NONE
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST (OUTPT ONLY)
Coverage Duration	14 DAYS
Other Criteria	IN THE OUTPATIENT SETTING, NUZYRA IS COVERED WHEN PRESCRIBED IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST. FOR PATIENTS DISCHARGED FROM AN INPATIENT SETTING ON NUZYRA THERAPY, THE PRESCRIBER RESTRICTION IS BYPASSED. REQUESTS FOR NON-FDA APPROVED DURATIONS OF THERAPY WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OCALIVA

Products Affected

- Ocaliva

PA Criteria	Criteria Details
Exclusion Criteria	PATIENTS WITH COMPLETE BILIARY OBSTRUCTION WILL BE EXCLUDED FROM COVERAGE.
Required Medical Information	DIAGNOSIS, DOCUMENTATION OF CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, PERTINENT LAB RESULTS (SUCH AS ALP LEVELS, BILIRUBIN, ANTIMICHONDRIAL ANTIBODY/AMA TEST)
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST OR HEPATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	OCALIVA WILL BE COVERED FOR THE DIAGNOSIS OF PRIMARY BILIARY CHOLANGITIS THAT HAS BEEN CONFIRMED BY 2 OF THE FOLLOWING: POSITIVE 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 URSODIOL, OCALIVA WILL BE COVERED WHEN PRESCRIBED IN

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OFEV

Products Affected

- Ofev

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS TO CONFIRM DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	OFEV WILL BE COVERED FOR A DOCUMENTED DIAGNOSIS OF IDIOPATHIC PULMONARY FIBROSIS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OLUMIANT

Products Affected

- Olumiant

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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
- Balversa
- Bosulif oral tablet 100 mg, 400 mg, 500 mg
- Braftovi oral capsule 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
- Inrebic
- 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
- Nubeqa
- Odomzo
- Piqray
- 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
- Xpovio oral tablet 100 mg/week (20 mg x 5), 160 mg/week (20 mg x 8), 60 mg/week (20 mg x 3), 80 mg/week (20 mg x 4)
- Xtandi
- Zejula

- Zelboraf
- Zolinza
- Zydelig
- Zykadia

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORENCIA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
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	PRESCRIBER MUST BE A RHEUMATOLOGIST
Coverage Duration	TWO YEARS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORENITRAM

Products Affected

- Orenitram

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, RIGHT HEART CATHETERIZATION RESULTS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR THE TREATMENT OF PULMONARY HYPERTENSION DIAGNOSED BY RIGHT HEART CATHETERIZATION SHOWING A MEAN ARTERY PRESSURE OF GREATER THAN OR EQUAL TO 25 MMHG AT REST. IN ADDITION, THE PATIENT MUST HAVE A PULMONARY CAPILLARY WEDGE PRESSURE LESS THAN OR EQUAL TO 15 MMHG AT REST. THERE MUST ALSO BE DOCUMENTATON OF CLINICAL FAILURE OR SEVERE INTOLERANCE TO GENERIC SILDENAFIL OR GENERIC TADALAFIL/ALYQ AND AN ENDOTHELIN RECEPTOR ANTAGONIST SUCH AS AMBRISENTAN, OPSUMIT, OR TRACLEER EITHER ALONE OR IN COMBINATION. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORFADIN

Products Affected

- Orfadin

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT THERAPIES, PERTINENT LAB/DIAGNOSTIC TEST RESULTS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN THE TREATMENT OF TYROSINEMIA TYPE 1 (SUCH AS A METABOLIC DISEASE SPECIALIST)
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR PATIENTS WITH A DIAGNOSIS OF HEREDITARY TYROSINEMIA TYPE 1. PATIENTS MUST HAVE THE PRESENCE OF SUCCINYACETONE (SSA) IN THE URINE OR BLOOD / DRIED BLOOD SPOTS. PATIENTS MUST HAVE CLINICAL FEATURES OF TYROSINEMIA TYPE 1, SUCH AS: FAILURE TO THRIVE, EMESIS, MELENA, HEPATOSPLENOMEGALY, LIVER DISEASE, CIRRHOSIS, CLOTTING ABNORMALITIES, RENAL DISEASE/FANCONI SYNDROME, NEUROLOGICAL CRISIS, RICKETS. COVERAGE OF ORFADIN REQUIRES DOCUMENTED INTOLERANCE OR CLINICAL FAILURE OF NITYR. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORILISSA

Products Affected

- Orilissa oral tablet 150 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR PATIENTS WITH SEVERE HEPATIC IMPAIRMENT (CHILD PUGH C) AND AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ORKAMBI

Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	COVERAGE WILL BE EXCLUDED IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE NOT HOMOZYGOUS FOR THE F508 DEL MUTATION IN THE CFTR GENE.
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING THAT SHOWS TWO COPIES OF THE F508 DEL MUTATION IN THE CONDUCTANCE REGULATOR (CFTR) GENE.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OSMOLEX ER

Products Affected

- Osmolex ER

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OTEZLA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE A DERMATOLOGIST OR RHEUMATOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

OXERVATE

Products Affected

- Oxervate

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN OPHTHALMOLOGIST
Coverage Duration	8 WEEKS
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PAIN MANAGEMENT

Products Affected

- Abstral
- fentanyl citrate
- 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
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PALYNZIQ

Products Affected

- Palynziq

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, SERUM PHENYLALANINE LEVELS, AND ANY OTHER PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS GENETIC TEST RESULTS) PERFORMED TO CONFIRM THE DIAGNOSIS.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A HEALTHCARE PROVIDER EXPERIENCED IN THE MANAGEMENT OF PKU
Coverage Duration	INITIAL APPROVAL 1 YEAR. 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.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

PRALUENT

Products Affected

- Praluent Pen

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST
Coverage Duration	LOWER DOSE: INITIAL APPROVAL 12 WKS. HIGHER DOSE: 1 YR. REFER TO OTHER CRITERIA FOR RECERT DURATION
Other Criteria	FOR ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), PT MUST HAVE A HX OF ACUTE CORONARY SYNDROME, MI,

PA Criteria	Criteria Details
	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. AUTHORIZATION FOR HIGHER DOSE PRALUENT WILL BE FOR 1 YR. ANNUAL RECERTIFICATION THEREAFTER WILL REQUIRE DOCUMENTATION OF A REDUCTION IN LDL FROM BASELINE FOR ALL DIAGNOSES. INITIAL AUTHORIZATION FOR LOWER DOSE PRALUENT WILL BE FOR 12 WKS FOR ALL DIAGNOSES. AT WK 12, IF THERE IS LDL REDUCTION FROM BASELINE, THEN AUTHORIZATION WILL BE GIVEN FOR 1 YR. AT WK 12, IF THERE IS NOT A REDUCTION IN LDL FROM BASELINE WHILE ON LOWER DOSE PRALUENT, THEN 12 WKS OF TX WITH HIGHER DOSE PRALUENT WILL BE AUTHORIZED. AT 24 WKS, AUTH WILL NOT BE EXTENDED IF THERE IS NOT A REDUCTION IN LDL FROM BASELINE. IF LDL REDUCTION FROM BASELINE IS ACHIEVED, THEN AUTHORIZATION WILL BE GIVEN FOR 1 YR. ANNUAL RECERTIFICATIONS THEREAFTER WILL REQUIRE DOCUMENTATION OF ONGOING LDL LEVELS BELOW BASELINE.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PROLIA

Products Affected

- Prolia

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS
Other Criteria	PATIENT MUST FALL INTO ONE OF THE FOLLOWING CATEGORIES: POSTMENOPAUSAL WOMAN, OSTEOPOROSIS IN A MALE OR PATIENT AT RISK FOR STEROID INDUCED OSTEOPOROSIS. PATIENT MUST ALSO BE AT HIGH RISK FOR A FRACTURE DEFINED AS 1) HISTORY OF PREVIOUS OSTEOPOROSIS-RELATED FRACTURE, 2) T- SCORE OF -2.5 SD OR LESS, 3) T-SCORE BETWEEN -1.0 AND -2.5 SD BELOW NORMAL AND A FRAX SCORE FOR HIP FRACTURE OF 3% OR GREATER OR THE RISK FOR OTHER BONE FRACTURE IS 20% OR GREATER. PATIENT MUST ALSO HAVE EXPERIENCED THERAPEUTIC FAILURE, SEVERE INTOLERANCE OR A CONTRAINDICATION TO AN ORAL BISPHOSPHONATE OR BE AN INAPPROPRIATE CANDIDATE FOR ORAL BISPHOSPHONATE THERAPY BASED ON CLINICAL PRESENTATION. THERAPEUTIC FAILURE IS DEFINED AS A DECREASE IN BONE MINERAL DENSITY OR A FRACTURE WHILE ON 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

PA Criteria	Criteria Details
	A PATIENT THAT IS BED-RIDDEN/UNABLE TO SIT UPRIGHT FOR 30 MINUTES UNSUPERVISED OR HAS ESOPHAGEAL ULCERATIONS, ESOPHAGEAL STRICTURE, BARRETT'S ESOPHAGITIS, OR ACTIVE ULCERS.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. REQUEST WILL ALSO BE EVALUATED FOR PART B VERSUS PART D COVERAGE AND OFF-LABEL USE.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PROMACTA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES. 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 ITP OR APLASTIC ANEMIA, MUST BE PRESCRIBED BY A HEMATOLOGIST. FOR THOMBOCYTOPENIA WITH HEP C, MUST BE PRESCRIBED BY GI, HEPATOLOGIST, ID, OR HCV/HIV SPECIALIST.
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. COVERED FOR A DIAGNOSIS OF THROMBOCYTOPENIA IN PATIENTS WITH CHRONIC HEPATITIS C TO ALLOW INITIATION AND MAINTENANCE OF INTERFERON-BASED THERAPY. COVERED FOR A DIAGNOSIS OF APLASTIC ANEMIA. IN ADDITION, THE PATIENT MUST HAVE EXPERIENCED AN INSUFFICIENT RESPONSE TO IMMUNOSUPPRESSIVE THERAPY SUCH AS

PA Criteria	Criteria Details
	ANTITHYMOCYTE GLOBULIN (ATG) ALONE OR IN COMBINATION WITH CYCLOSPORINE AND/OR A CORTICOSTEROID. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PULMONARY HYPERTENSION

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS, RIGHT HEART CATHETERIZATION RESULTS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A PULMONOLOGIST OR CARDIOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PULMOZYME

Products Affected

- Pulmozyme

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

QUDEXY XR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

QUININE SULFATE

Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR THE TREATMENT OF LEG CRAMPS
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	6 MONTHS
Other Criteria	QUININE SULFATE IS COVERED FOR THE TREATMENT OF MALARIA INFECTIONS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RAVICTI

Products Affected

- Ravicti

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY PHYSICIAN EXPERIENCED IN THE MANAGEMENT OF UREA CYCLE DISORDERS
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RELISTOR

Products Affected

- Relistor oral
- Relistor subcutaneous solution
- Relistor subcutaneous syringe

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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 TAKEN AFTER 4-8 WEEKS ON TREATMENT MUST BE SUBMITTED FOR REVIEW.

PA Criteria	Criteria Details
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGIST
Coverage Duration	ONE YEAR
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 AND/OR LAB ABNORMALITIES RETURNED TO NORMAL.REPATHA WILL NOT BE APPROVED IN COMBO WITH JUXTAPID OR KYNAMRO. AUTHORIZATION WILL BE FOR 1 YR. ANNUAL RECERTIFICATION THEREAFTER WILL REQUIRE

PA Criteria	Criteria Details
	DOCUMENTATION OF A REDUCTION IN LDL VERSUS BASELINE FOR ALL DIAGNOSES.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

REXULTI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RINVOQ

Products Affected

- Rinvoq ER

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA LABELING
Required Medical Information	DIAGNOSIS, CONCURRENT MEDICATIONS, PREVIOUS DRUGS TRIED.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A RHEUMATOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	COVERED IN PATIENTS WITH ACTIVE MODERATE TO SEVERE RHEUMATOID ARTHRITIS WHO HAVE FAILED TO RESPOND TO AND/OR ARE INTOLERANT OF APPROVED DISEASE-MODIFYING ANTIRHEUMATIC DRUG (DMARD) AGENTS, SUCH AS METHOTREXATE, AZATHIOPRINE, SULFASALAZINE, OR HYDROXYCHLOROQUINE, EITHER ALONE OR IN COMBINATION, FOR A 3-MONTH PERIOD.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

RUCONEST

Products Affected

- Ruconest

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR THE PROPHYLAXIS OF HEREDITARY ANGIOEDEMA ATTACKS. EXCLUDED FOR THE TREATMENT OF ACUTE LARYNGEAL 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 ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A CONFIRMED DIAGNOSIS OF HAE TYPE 1, TYPE II, OR TYPE III FOR THE TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACKS. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SAMSCA

Products Affected

- Samsca

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SHINGRIX

Products Affected

- Shingrix (PF)

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR INDIVIDUALS UNDER THE AGE OF 50
Required Medical Information	DIAGNOSIS
Age Restrictions	PA APPLIES FOR PATIENTS AGED 49 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	Pending CMS Review
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST
Coverage Duration	INITIAL 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SILIQ

Products Affected

- Siliq

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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, SKYRIZI, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SIMPONI

Products Affected

- Simponi

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SIVEXTRO

Products Affected

- Sivextro

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS (SUCH AS BACTERIAL CULTURES OR ANTIBIOTIC SENSITIVITY TESTING), AND DOCUMENTATION OF PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	6 DAYS
Other Criteria	SIVEXTRO IS COVERED WHEN PRESCRIBED OR RECOMMENDED BY AN INFECTIOUS DISEASE SPECIALIST. WHEN PRESCRIBED BY ANY OTHER PRESCRIBER, LABORATORY DATA INCLUDING CULTURE SITE, ORGANISM IDENTIFIED AND SUSCEPTIBILITY MUST ACCOMPANY PRIOR-AUTHORIZATION REQUEST AND DOCUMENTATION MUST SUPPORT THE TRIAL. IN ADDITION, DOCUMENTATION OF THERAPEUTIC FAILURE OF AT LEAST ONE FIRST-LINE ANTIBACTERIAL AGENT THAT IS CLINICALLY APPROPRIATE FOR THE ORGANISM IDENTIFIED MUST BE SUBMITTED. APPROVAL WILL BE FOR 6 DAYS OF THERAPY. REQUESTS FOR NON-FDA APPROVED DURATIONS OF THERAPY WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SKYRIZI

Products Affected

- Skyrizi subcutaneous syringe kit

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A DERMATOLOGIST
Coverage Duration	TWO YEARS
Other Criteria	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 ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SOVALDI

Products Affected

- Sovaldi

PA Criteria	Criteria Details
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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	12 TO 48 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE)
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SPRITAM

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES USED FOR THE TREATMENT OF THE STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

STELARA

Products Affected

- Stelara subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
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 SEVERELY ACTIVE CROHN'S DISEASE. IN ADDITION, THE PATIENT MUST MEET ONE OF THE FOLLOWING CRITERIA: 1)

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SUNOSI

Products Affected

- Sunosi oral tablet 150 mg, 75 mg

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA LABELING
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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A NEUROLOGIST OR SLEEP SPECIALIST FOR A DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY. MUST BE PRESCRIBED BY A NEUROLOGIST, SLEEP SPECIALIST, OR PULMONOLOGIST FOR A DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA.
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR A DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY OR OBSTRUCTIVE SLEEP APNEA (OSA). FOR OSA, PRESCRIBER MUST ATTEST THAT THE PATIENT'S UNDERLYING AIRWAY OBSTRUCTION HAS BEEN TREATED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) FOR AT LEAST 1 MONTH PRIOR TO INITIATING SUNOSI. IN ADDITION TO HAVING ONE OF THE ABOVE DIAGNOSES, THERE MUST ALSO BE DOCUMENTATION OF CLINICAL FAILURE OR SEVERE INTOLERANCE OF BOTH ARMODANAFIL AND MODAFINIL. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYMDEKO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	COVERAGE WILL BE EXCLUDED IN PATIENTS THAT LACK THE REQUIRED GENETIC MUTATION(S) TARGETED BY THE MEDICATION
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC RESULTS TO INCLUDE TESTING THAT SHOWS EITHER TWO COPIES OF THE F508 DEL MUTATION IN THE CONDUCTANCE REGULATOR (CFTR) GENE OR AT LEAST ONE MUTATION IN THE CFTR GENE THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR (SYMDEKO) 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYMPROIC

Products Affected

- Symproic

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

SYNDROS

Products Affected

- Syndros

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS. FOR A DIAGNOSIS OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY, ALSO LIST PREVIOUS THERAPIES.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ANOREXIA DUE TO AIDS-1 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TADALAFIL FOR DAILY USE

Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	TADALAFIL FOR DAILY USE WILL NOT BE COVERED FOR THE INDEPENDENT DIAGNOSIS OF ERECTILE DYSFUNCTION. TADALAFIL IS EXCLUDED FOR OFF-LABEL INDICATIONS EVEN IF SUPPORTED BY AHFS OR DRUGDEX COMPENDIA.
Required Medical Information	DIAGNOSIS, 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	ONE YEAR
Other Criteria	COVERED FOR A DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAKHZYRO

Products Affected

- Takhzyro

PA Criteria	Criteria Details
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	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TALTZ

Products Affected

- Taltz Autoinjector
- Taltz Syringe

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES 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 OR RHEUMATOLOGIST
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, SKYRIZI, STELARA. TALTZ IS COVERED FOR PATIENTS WITH A DIAGNOSIS OF PSORIATIC ARTHRITIS WITH DOCUMENTED FAILURE OF TWO OF THE FOLLOWING ALTERNATIVES, COSENTYX, ENBREL, HUMIRA, OTEZLA, ORENCIA, STELARA, XELJANZ, XELJANZ XR. REQUESTS FOR NON FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TAVALISSE

Products Affected

- Tavalisse

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TEGSEDI

Products Affected

- Tegsedi

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED IN PATIENTS WITH A PLATELET COUNT LESS THAN 100 X 10 TO THE 9TH PER LITER OR HISTORY OF ACUTE GLOMERULONEPHRITIS CAUSED BY TEGSEDI
Required Medical Information	DIAGNOSIS WITH CONFIRMATION OF THE TRANSTHYRETIN (TTR) GENE MUTATION
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A SPECIALIST EXPERIENCED IN THE DIAGNOSIS OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (HATTR), SUCH AS A HEMATOLOGIST, ONCOLOGIST, NEUROLOGIST, GASTROENTEROLOGIST, GENETICIST, OR NEPHROLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR TREATMENT OF POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (HATTR) WHEN THE DIAGNOSIS HAS BEEN CONFIRMED BY MUTATION OF THE TRANSTHYRETIN (TTR) GENE. PATIENTS MUST ALSO HAVE SYMPTOMS CONSISTENT WITH POLYNEUROPATHY, WHICH CAN INCLUDE EITHER PERIPHERAL SENSORIMOTOR POLYNEUROPATHY SYMPTOMS (SUCH AS TINGLING OR INCREASED PAIN IN THE HANDS/FEET/ARMS, LOSS OF FEELING IN THE HANDS/FEET, NUMBNESS OR TINGLING IN THE WRISTS, CARPAL TUNNEL SYNDROME, LOSS OF ABILITY TO SENSE TEMPERATURE, DIFFICULTY WITH FINE MOTOR SKILLS, WEAKNESS IN THE LEGS, DIFFICULTY WALKING, SEIZURES, HEADACHES) OR AUTONOMIC NEUROPATHY SYMPTOMS (SUCH AS ORTHOSTASIS, ABNORMAL SWEATING, SEXUAL DYSFUNCTION, RECURRENT URINARY TRACT INFECTION, DYSAUTONOMIC SYMPTOMS OF CONSTIPATION, DIARRHEA,

PA Criteria	Criteria Details
	NAUSEA, VOMITING, ANOREXIA, AND EARLY SATIETY). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

THALOMID

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TOPICAL PSORIASIS COMBOS

Products Affected

- Duobrii
- Enstilar
- Taclonex topical suspension

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS
Other Criteria	COVERED FOR A DIAGNOSIS OF PSORIASIS. IN ADDITION, THERE MUST BE LACK OF CLINICAL RESPONSE OR INTOLERANCE TO ONE TOPICAL STEROID AND EITHER A TOPICAL VITAMIN D ANALOG OR A TOPICAL RETINOID. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TOPICAL RETINOIDS

Products Affected

- adapalene topical cream
- adapalene topical gel
- adapalene topical solution
- adapalene topical swab
- Altreno
- Avita
- Differin topical lotion
- Fabior
- Retin-A Micro topical gel with pump 0.06 %, 0.08 %
- tazarotene
- Tazorac topical cream 0.05 %
- Tazorac topical gel
- tretinoin microspheres topical gel
- tretinoin topical

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED WHEN USED FOR COSMETIC PURPOSES
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND DOCUMENTATION OF ANY 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	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TREMFYA

Products Affected

- Tremfya

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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, SKYRIZI, STELARA. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TROKENDI XR

Products Affected

- Trokendi XR

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TURALIO

Products Affected

- Turalio

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ONCOLOGIST OR HEMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR PATIENTS WITH A DIAGNOSIS OF SYMPTOMATIC TENOSYNOVIAL GIANT CELL TUMOR (TGCT, ALSO REFERRED TO AS PIGMENTED VILLONODULAR SYNOVITIS OR GIANT CELL TUMOR OF THE TENDON). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

TYMLOS

Products Affected

- Tymlos

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, DEXA SCAN REPORT(S), PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	TWO YEARS (REFER TO OTHER CRITERIA SECTION)
Other Criteria	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-RIDDEN/UNABLE TO SIT UPRIGHT FOR 30 MINUTES

PA Criteria	Criteria Details
	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

UCERIS FOAM

Products Affected

- Uceris rectal

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DOCUMENTATION OF DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, AND DOCUMENTATION OF PREVIOUS THERAPIES (IF APPLICABLE).
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ONCOLOGIST OR DERMATOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VIEKIRA

Products Affected

- Viekira Pak

PA Criteria	Criteria Details
Exclusion Criteria	VIEKIRA WILL NOT BE COVERED IN PATIENTS WITH MODERATE TO SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C). VIEKIRA 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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	12 TO 24 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE)
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VOSEVI

Products Affected

- Vosevi

PA Criteria	Criteria Details
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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VRAYLAR

Products Affected

- Vraylar oral capsule
- Vraylar oral capsule,dose pack

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

VYNDAQEL

Products Affected

- Vyndaqel

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR NYHA FUNCTIONAL CLASS IV AND AS LIMITED BY FDA LABELING
Required Medical Information	DIAGNOSIS, PERTINENT LAB/DIAGNOSTIC TESTS, INCLUDING TESTS CONFIRMING PRESENCE OF TTR AMYLOID IN CARDIAC TISSUE SUCH AS 99MTECHNETIUM-LABELED PYROPHOSPHATE CARDIAC IMAGING TEST RESULTS (NUCLEAR SCINTIGRAPHY) POSITIVE FOR TTR AMYLOID OR GENETIC TESTING/NEXT-GENERATION SEQUENCING CONFIRMING A VARIANT TTR GENOTYPE AND/OR TTR PRECURSOR PROTEIN
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A SPECIALIST EXPERIENCED IN THE DIAGNOSIS OF TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM), SUCH AS A CARDIOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR PATIENTS WITH A DIAGNOSIS OF CARDIOMYOPATHY OF WILD TYPE (HATTR-CM) OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTRWT-CM). PATIENT MUST HAVE A MEDICAL HISTORY OF HEART FAILURE WITH AT LEAST ONE PRIOR HOSPITALIZATION FOR HEART FAILURE OR CLINICAL EVIDENCE OF HEART FAILURE REQUIRING TREATMENT WITH A DIURETIC FOR IMPROVEMENT. UPON RECERTIFICATION, THERE MUST BE DOCUMENTATION THAT THE PATIENT CONTINUES TO OBTAIN CLINICAL BENEFIT FROM THE THERAPY. REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XELJANZ

Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES FOR STATED DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN APPROPRIATE SPECIALIST TO TREAT THE STATED DIAGNOSIS
Coverage Duration	TWO YEARS
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.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

XENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	AS LIMITED BY FDA-LABELING
Required Medical Information	DIAGNOSIS
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	NONE
Coverage Duration	ONE YEAR
Other Criteria	REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	FOR THE TREATMENT OF CARCINOID SYNDROME DIARRHEA, COVERAGE WILL NOT BE PROVIDED IN THE ABSENCE OF CONCURRENT SOMASTATIN ANALOG THERAPY (LANREOTIDE OR OCTREOTIDE).
Required Medical Information	DIAGNOSIS, CURRENT AND PREVIOUS THERAPIES 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 ONCOLOGIST, HEMATOLOGIST, ENDOCRINOLOGIST, OR GASTROENTEROLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR THE TREATMENT OF CARCINOID SYNDROME DIARRHEA WITH DOCUMENTATION OF CONTINUED DIARRHEA DESPITE A MINIMUM 3-MONTH TRIAL OF SOMASTATIN ANALOG THERAPY (LANREOTIDE OR OCTREOTIDE). REQUESTS FOR NON-FDA APPROVED INDICATIONS WILL BE EVALUATED ACCORDING TO THE MEDICARE STATUTORY OFF-LABEL USE REQUIREMENTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XGEVA

Products Affected

- Xgeva

PA Criteria	Criteria Details
Exclusion Criteria	XGEVA WILL NOT BE APPROVED FOR USE IN COMBINATION WITH ORAL OR INJECTABLE BISPHOSPHONATES.
Required Medical Information	DOCUMENTATION OF DIAGNOSIS. FOR A DIAGNOSIS OF BONE METASTASIS FROM SOLID TUMOR, PROVIDE RADIOGRAPHIC EVIDENCE (X-RAY, CT, OR MRI) OF A LEAST ONE BONE METASTASIS.
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ONCOLOGIST
Coverage Duration	ONE YEAR
Other Criteria	COVERED FOR THE PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA AND IN PATIENTS WITH BONE METASTASES FROM SOLID TUMORS FOR WHICH THERE IS RADIOGRAPHIC EVIDENCE OF AT LEAST ONE BONE METASTASIS. APPROVED FOR TREATMENT OF GIANT CELL TUMOR OF THE BONE (IN ADULTS AND SKELETALLY MATURE ADOLESCENTS) THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY. APPROVED FOR THE TREATMENT OF HYPERCALCEMIA OF MALIGNANCY REFRACTORY TO BISPHOSPHONATE THERAPY.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
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	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, DERMATOLOGIST, IMMUNOLOGIST, OR PULMONOLOGIST
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 HAVE A CONTRAINDICATION TO CONTROLLER MEDICATIONS INDICATED IN THE NHLBI GUIDELINES. FOR PATIENTS AGES 12 AND OLDER, PT MUST HAVE BASELINE IGE LEVELS BETWEEN 30 AND 700 IU/ML. FOR PATIENTS AGES 6 AND LESS THAN 12, PT 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. IF ABOVE CRITERIA IS

PA Criteria	Criteria Details
	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. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

XYREM

Products Affected

- Xyrem

PA Criteria	Criteria Details
Exclusion Criteria	USE OF XYREM TO TREAT INSOMNIA IS EXCLUDED
Required Medical Information	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	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

YONSA

Products Affected

- Yonsa

PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZEPATIER

Products Affected

- Zepatier

PA Criteria	Criteria Details
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 AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HCV/HIV SPECIALIST
Coverage Duration	12 TO 16 WEEKS (DEPENDING ON DIAGNOSIS, FDA-APPROVED LABELING, AND AASLD/IDSA GUIDANCE)
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZONTIVITY

Products Affected

- Zontivity

PA Criteria	Criteria Details
Exclusion Criteria	HISTORY OF STROKE, TRANSIENT ISCHEMIC ATTACK, OR INTRACRANIAL HEMORRHAGE OR CURRENT ACTIVE PATHOLOGICAL BLEEDING (SUCH AS INTRACRANIAL HEMORRHAGE, PEPTIC ULCER BLEEDING).
Required Medical Information	DOCUMENTATION OF DIAGNOSIS AND HISTORY OF MYOCARDIAL INFARCTION AND/OR PERIPHERAL ARTERIAL DISEASE, PERTINENT LAB/DIAGNOSTIC TEST RESULTS, AND DOCUMENTATION OF PREVIOUS THERAPIES
Age Restrictions	PATIENT AGE MUST BE CONSISTENT WITH THE FDA-APPROVAL FOR THE STATED DIAGNOSIS
Prescriber Restrictions	MUST BE PRESCRIBED BY A 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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

ZOSTAVAX AGE EDIT

Products Affected

- Zostavax (PF)

PA Criteria	Criteria Details
Exclusion Criteria	EXCLUDED FOR INDIVIDUALS UNDER THE AGE OF 50
Required Medical Information	DIAGNOSIS
Age Restrictions	PA APPLIES FOR PATIENTS AGED 49 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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 %), 2.5 mg/0.5 mL
- AmBisome
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- 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 oral capsule
- CellCept oral tablet
- Clinimix 5%/D15W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix E 2.75%/D5W Sulf Free
- Clinimix E 4.25%/D10W 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 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)
- insulin lispro subcutaneous solution
- 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 oral capsule
- 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 %
- RabAvert (PF)
- Rapamune oral tablet
- Rayos
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral
- sirolimus
- tacrolimus oral
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- trimethobenzamide oral
- TrophAmine 10 %
- Trophamine 6%
- Varubi oral
- Xatmep
- Yupelri
- 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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