HealthPartners®

2024 Medicare Part D
Prior Authorization Requirements

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ABIRATERONE

MEDICATION(S)
ABIRATERONE ACETATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND, (2) IF THE REQUEST IS FOR 500 MG TABLET, PLEASE PROVIDE A RATIONALE WHY PATIENT CANNOT USE THE 250 MG TABLET. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ACTEMRA

MEDICATION(S)
ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ACTEMRA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) GIANT CELL ARTERITIS IN COMBINATION WITH TAPERING COURSE OF CORTICOSTEROIDS OR AS SINGLE AGENT FOLLOWING DISCONTINUATION OF CORTICOSTEROIDS, OR (2) SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: METHOTREXATE, LEFLUNOMIDE, HYDROXYCHLOROQUINE OR SULFASALAZINE, OR (3) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (4) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HADLIMA, AND HUMIRA, OR (5) SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD) (EARLY DIFFUSE SSC AND ILD, AND EARLY EVIDENCE OF ILD PROGRESSION) WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO MYCOPHENOLATE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, IMMUNOLOGIST OR PULMONOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ACTIMMUNE

MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A MAXIMUM DOSE OF 50 MCG PER SQUARE METER 3 TIMES WEEKLY.

PART B PREREQUISITE
N/A

AJOVY

MEDICATION(S)
AJOVY AUTOINJECTOR, AJOVY SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH OTHER CGRP ANTAGONISTS FOR MIGRAINE PREVENTION (SUCH AS EMGALITY).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: FOR THE DIAGNOSIS OF MIGRAINE PREVENTION, THE PATIENT HAS A DOCUMENTED INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ANDROGEN THERAPY

MEDICATION(S)
TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 50 MG/5 GRAM GEL, TESTOSTERONE 50 MG/5 GRAM PKT, TESTOSTERONE CYPIONATE, TESTOSTERONE ENANTHATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTED TESTOSTERONE DEFICIENCY OF LESS THAN 300 NG/DL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANTICONVULSANTS - SELECT AGENTS

MEDICATION(S)
APTIOM, FYCOMPA, LIBERVANT, RUFINAMIDE, ZONISADE, ZTALMY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY NEUROLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANTIDEPRESSANTS - NON-PREFERRED AGENTS

MEDICATION(S)
AUVELITY, DRIZALMA SPRINKLE, FETZIMA, TRINTELLIX, VIIBRYD 10-20 MG STARTER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO PREFERRED ALTERNATIVE ANTIDEPRESSANTS, SUCH AS: CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, VENLAFAXINE, OR DULOXETINE, OR (3) FOR DRIZALMA, FOR THE DIAGNOSES OF DIABETIC PERIPHERAL NEUROPATHY AND CHRONIC MUSCULOSKELETAL PAIN, DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO DULOXETINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANTINEOPLASTIC INJECTABLES

MEDICATION(S)
BESREMI, FULVESTRANT, LEUPROLIDE DEPOT, LUPRON DEPOT, POLIVY, TECENTRIQ HYBREZA, TRELSTAR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, OR (2) DOCUMENTATION THAT A PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: DOCUMENTATION OF A BENEFICIAL RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS) OR DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) WITH GENETIC TESTING CONFIRMING MUTATION IN THE IL1RN GENE, AND DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO KINERET OR (2) DIAGNOSIS OF RECURRENT PERICARDITIS, AND DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TWO OF THE FOLLOWING THERAPIES: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS, COLCHICINE OR CORTICOSTEROIDS. RENEWAL CRITERIA: (1) REAUTHORIZATIONS WILL REQUIRE MEDICAL CHART DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) PROVIDER ATTESTATION OF CLINICAL IMPROVEMENT AND THAT THE MEDICATION CONTINUES TO BE EFFECTIVE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH A SPECIALIST.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

ATYPICAL ANTIPSYCHOTIC AGENTS

MEDICATION(S)
CAPLYTA, FANAPT, LYBALVI, MOLINDONE HCL, REXULTI 0.25 MG TABLET, REXULTI 0.5 MG TABLET, REXULTI 1 MG TABLET, REXULTI 2 MG TABLET, REXULTI 3 MG TABLET, REXULTI 4 MG TABLET, SECUADO, VRAYLAR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO OF THE FOLLOWING ALTERNATIVES: RISPERIDONE, ZIPRASIDONE, OLANZAPINE, QUETIAPINE REGULAR RELEASE, QUETIAPINE EXTENDED RELEASE OR ARIPIPRAZOLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

AUSTEDO

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR TITRATION KT(WK1-4)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

BAFIERTAM

MEDICATION(S)
BAFIERTAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO DIMETHYL FUMARATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

BRIVIACT

MEDICATION(S)
BRIVIACT 10 MG TABLET, BRIVIACT 10 MG/ML ORAL SOLN, BRIVIACT 100 MG TABLET, BRIVIACT 25 MG TABLET, BRIVIACT 50 MG TABLET, BRIVIACT 75 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO LEVETIRACETAM AND ONE ADDITIONAL PREFERRED SEIZURE MEDICATION, SUCH AS LAMOTRIGINE, CARBAMAZEPINE, DIVALPROEX, PHENYTOIN, TOPIRAMATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BRONCHITOL

MEDICATION(S)
BRONCHITOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
FAILURE TO PASS THE BRONCHITOL TOLERANCE TEST

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) BRONCHITOL HAS BEEN PRESCRIBED AS AN ADD-ON MAINTENANCE THERAPY FOR CYSTIC FIBROSIS, AND (2) PATIENT HAS AN FEV1 GREATER THAN 40% AND LESS THAN 90% PREDICTED (A BASELINE FEV1 MUST BE PROVIDED AT THE TIME OF THE REQUEST). RENEWAL CRITERIA: DOCUMENTATION THAT THE MEDICATION CONTINUES TO BE EFFECTIVE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

CABLIVI

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
THROMBOCYTOPENIA DUE TO ANOTHER CAUSE, INCLUDING SEPSIS, INFECTION WITH E. COLI 0157, ATYPICAL HEMOLYTIC UREMIC SYNDROME, DISSEMINATED INTRAVASCULAR COAGULATION, OR CONGENITAL THROMBOTIC THROMBOCYTOPENIC PURPURA.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT IS AN ADULT DIAGNOSED WITH ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (ATTP) INCLUDING THE FOLLOWING: (A) THROMBOCYTOPENIA WITH PLATELET COUNT LESS THAN 100,000/MICROL (100X10E9/L), AND (B) INCLUDES MICROSCOPIC EVIDENCE OF RED BLOOD CELL FRAGMENTATION (E.G., SCHISTOCYTES) (2) DOCUMENTATION OF ONE OF THE FOLLOWING RELATED TO ADAMTS13: (A) SEVERE ADAMTS13 DEFICIENCY (ACTIVITY LEVELS OF LESS THAN 10%), OR (B) ADAMTS DEFICIENCY (ACTIVITY LEVELS OF GREATER THAN 10% BUT LESS THAN 30%), WITH CLINICAL RATIONALE SUPPORTING THE DIAGNOSIS OF ATTP, OR (C) ADAMTS13 HAS BEEN ORDERED BUT LAB RESULTS ARE NOT YET AVAILABLE, AND (4) PRESCRIBED IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY (SUCH AS HIGH-DOSE GLUCOCORTICOIDS AND/OR RITUXIMAB, AND (5) CABLIVI WILL BE DISCONTINUED IF PATIENT EXPERIENCES MORE THAN 2 RECURRENCES OF ATTP WHILE ON CABLIVI. RENEWAL CRITERIA: PATIENT WAS PREVOIUSLY TREATED SUCCESSFULLY WITH CABLIVI AND CONTINUES TO MEET INITIAL CRITERIA FOR A SUBSEQUENT EPISODE.

AGE RESTRICTION
LIMITED TO ADULTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY HEMATOLOGY/ONCOLOGY

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

CENEGERMIN

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF NEUROTROPHIC KERATITIS, AND (2) PROVIDER ATTESTATION THAT PATIENT HAS BEEN EDUCATED ON ADMINISTRATION TECHNIQUE, DRUG STORAGE, AND DRUG PREPARATION REQUIREMENTS, AND (3) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO PROPHYLACTIC ANTIBIOTICS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 2 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST.

COVERAGE DURATION
8 WKS PER FDA LABELING.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. CONTINUATION THERAPY OR RETREATMENT IS NOT ALLOWED FOR THE SAME AFFECTED EYE.

PART B PREREQUISITE
N/A

CIMZIA

MEDICATION(S)
CIMZIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CIMZIA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (2) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, STELARA, TREMFYA, RINVOQ, SKYRIZI AND COSENTYX, OR (3) PLAQUE PSORIASIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, COSENTYX, STELARA, TREMFYA AND SKYRIZI, OR (4) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, RINVOQ AND COSENTYX, OR (5) CROHN'S DISEASE WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE STELARA, SKYRIZI, RINVOQ, HADLIMA, AND HUMIRA, OR (6) DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS WITH SIGNS OF INFLAMMATION WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE PREFERRED DRUG: COSENTYX OR RINVOQ. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR GASTROENTEROLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

CINRYZE

MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CINRYZE CONCURRENTLY WITH OTHER BIOLOGIC PROPHYLACTIC THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS WHO HAVE (1) A DIAGNOSIS OF HEREDITARY ANGIOEDEMA (HAE), AND (2) DOCUMENTATION OF FAILURE OR MEDICAL CONTRAINDICATION TO TAKHZYRO, AND (3) DOCUMENTATION OF A HAE MANAGEMENT PLAN AND USE OF THIS THERAPY IS IN ACCORDANCE WITH THAT PLAN. RENEWAL CRITERIA: (1) MEDICAL CHART DOCUMENTATION OF THE NUMBER AND SEVERITY OF HAE ATTACKS OCCURRING IN THE PREVIOUS 6 MONTHS, AND (2) PATIENT HAS EXPERIENCED A REDUCTION IN THE NUMBER OF HAE ATTACKS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A HEMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.

COVERAGE DURATION
SIX MONTHS, THEN EVERY SIX MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

COSENTYX

MEDICATION(S)
COSENTYX (2 SYRINGES), COSENTYX SENSOREADY (2 PENS), COSENTYX SENSOREADY PEN, COSENTYX SYRINGE, COSENTYX UNOREADY PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE COSENTYX CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) PSORIATIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR ONE MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (2) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (3) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (4) DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS WITH SIGNS OF INFLAMMATION AND DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, OR (5) DIAGNOSIS OF ENTHESITIS-RELATED ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: ONE NSAID, SULFASALAZINE, OR METHOTREXATE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

CROMOLYN

MEDICATION(S)
CROMOLYN 100 MG/5 ML ORAL CONC

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: PATIENT HAS TRIED AND FAILED ONE OF THE FOLLOWING: (A) CONCURRENT USE OF BOTH H1 AND H2 ANTIHISTAMINE THERAPIES (SUCH AS HYDROXYZINE WITH FAMOTIDINE), OR (B) ANTILEUKOTRIENE THERAPY (SUCH AS MONTELUKAST). RENEWAL CRITERIA: DOCUMENTATION OF SYMPTOMATIC IMPROVEMENT.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN ALLERGIST OR SPECIALIST.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

CYSTARAN

MEDICATION(S)
CYSTADROPS, CYSTARAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF CYSTINOSIS. RENEWAL CRITERIA: DOCUMENTATION OF CLINICAL TREATMENT EFFECT (SUCH AS DOCUMENTATION OF SLIT LAMP EXAM RESULTS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, OR FOR OPHTHALMOLOGY SPECIALISTS.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

DALFAMPRIDINE ER

MEDICATION(S)
DALFAMPRIDINE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, (2) DOCUMENTATION THAT THE PATIENT IS CURRENTLY ABLE TO WALK 25 FEET, AND (3) PHYSICIAN ATTESTATION THAT PATIENT HAS DIFFICULTY WALKING. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

DIFICID

MEDICATION(S)
DIFICID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF CLOSTRIDIUM DIFFICILE INFECTION, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A COURSE OF ORAL VANCOMYCIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
10 DAYS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

DIHYDROERGOTAMINE

MEDICATION(S)
DIHYDROERGOTAMINE MESYLATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH TWO TRIPTAN MEDICATIONS SUCH AS SUMATRIPTAN, NARATRIPTAN OR RIZATRIPTAN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE DUPIXENT CONCURRENTLY WITH ANOTHER BIOLOGIC THERAPY FOR THE TREATMENT OF ASTHMA SUCH AS CINQAIR, NUCALA, FASENRA OR XOLAIR.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. FOR ATOPIC DERMATITIS: (1) MEDICAL CHART DOCUMENTATION OF MODERATE TO SEVERE ATOPIC DERMATITIS WITH AT LEAST 10% BODY SURFACE AREA (BSA) OR INVOLVEMENT WITH THE FACE, NECK, HANDS, FEET, OR GENITALS, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID OR ONE TOPICAL CALCINEURIN INHIBITOR (SUCH AS TACROLIMUS, PIMECROLIMUS). FOR ASTHMA: (1) MEDICAL CHART DOCUMENTATION OF EOSINOPHILIC OR ORAL CORTICOSTEROID DEPENDENT MODERATE TO SEVERE ASTHMA, AND (2) FOR EOSINOPHILIC ASTHMA, PRE-TREATMENT SERUM EOSINOPHIL COUNT OF 150 CELLS/MCL OR GREATER AT SCREENING (WITHIN THE PREVIOUS 12 MONTHS), AND (3) PATIENT HAS INADEQUATE ASTHMA CONTROL DESPITE USE OF AN INHALED STEROID (SUCH AS FLUTICASONE PROPIONATE HFA), AND AT LEAST ONE OTHER MAINTENANCE MEDICATION: (A) LEUKOTRIENE RECEPTOR ANTAGONIST, (B) LONG-ACTING BETA-AGONIST (SUCH AS SEREVENT), (C) LONG-ACTING MUSCARINIC ANTAGONIST (SUCH AS INCRUSE ELLIPTA), OR (D) THEOPHYLLINE, AND (4) INADEQUATE ASTHMA CONTROL DESPITE STANDARD THERAPIES IS DEFINED AS ONE OF THE FOLLOWING: (A) AT LEAST ONE EXACERBATION REQUIRING ORAL SYSTEMIC CORTICOSTEROIDS IN THE LAST 12 MONTHS, OR (B) AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT IN THE LAST 12 MONTHS. FOR CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: (1) PATIENT IS CURRENTLY RECEIVING THERAPY WITH AN INTRANASAL CORTICOSTEROID OR HAS TRIED AND FAILED OR HAS A

MEDICAL CONTRAINDICATION TO INTRANASAL CORTICOSTEROIDS. FOR EOSINOPHILIC ESOPHAGITIS (EOE): (I) MEDICAL CHART DOCUMENTATION OF EOE CONFIRMED BY ESOPHAGOGASTRODUODENOSCOPY (EGD) WITH BIOPSY, AND (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE PROTON PUMP INHIBITOR OR SWALLOWED TOPICAL STEROIDS (SUCH AS BUDESONIDE).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH AN ASTHMA SPECIALIST, ALLERGIST, PULMONOLOGIST, IMMUNOLOGIST, DERMATOLOGIST, GASTROENTEROLOGIST, OR OTOLARYNGOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. INITIAL CRITERIA: FOR PRURIGO NODULARIS: (I) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TOPICAL CORTICOSTEROID THERAPY, OR TOPICAL CALCIPOTRIOL. RENEWAL CRITERIA: (1) FOR NASAL POLYPS, DOCUMENTATION OF POSITIVE RESPONSE. (2) FOR ASTHMA, (A) CONTINUED USE OF AN INHALED STEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, (B) PATIENT HAS A POSITIVE RESPONSE AS DEFINED BY ONE OF THE FOLLOWING: (I) DECREASED FREQUENCY OF EXACERBATIONS (II) DECREASED USE OF RESCUE MEDICATIONS, (III) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (IV) IMPROVEMENT IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. (3) FOR EOSINOPHILIC ESOPHAGITIS, DOCUMENTATION OF POSITIVE RESPONSE. (4) FOR PRURIGO NODULARIS, DOCUMENTATION OF POSITIVE RESPONSE. (5) FOR ATOPIC DERMATITIS, MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

PART B PREREQUISITE

N/A

EMGALITY

MEDICATION(S)
EMGALITY PEN, EMGALITY SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH OTHER CGRP ANTAGONISTS FOR MIGRAINE PREVENTION (SUCH AS AJOVY).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) FOR THE DIAGNOSIS OF MIGRAINE PREVENTION, THE PATIENT HAS A DOCUMENTED INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, OR (2) THE PATIENT HAS A DIAGNOSIS OF EPISODIC CLUSTER HEADACHES. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
INITIAL: MIGRAINE PREVENTION: 6 MOS. EPISODIC CLUSTER HEADACHE: 3 MOS. RENEWAL (ALL): 12 MOS.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

EMSAM

MEDICATION(S)
EMSAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE PREFERRED DRUG FROM EACH OF THE FOLLOWING TWO ANTIDEPRESSANT SUB-CLASSES: (A) SSRI'S SUCH AS CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, AND (B) SNRI'S SUCH AS VENLAFAXINE OR DULOXETINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ENBREL CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) RHEUMATOID ARTHRITIS WITH: (I) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH HIGH DISEASE ACTIVITY AND POOR PROGNOSIS, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS OR PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (4) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

ENDARI

MEDICATION(S)
L-GLUTAMINE 5 GRAM POWDER PKT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT HAS BEEN DIAGNOSED WITH SICKLE CELL DISEASE, AND (2) PATIENT HAS EXPERIENCED TWO OR MORE PAINFUL CRISES WITHIN THE PREVIOUS 12 MONTHS DESPITE THE USE OF HYDROXYUREA, UNLESS HYDROXYUREA IS CONTRAINDICATED. RENEWAL CRITERIA: DOCUMENTATION THAT THE PATIENT HAS POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 5 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ENSPRYNG

MEDICATION(S)
ENSPRYNG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ENSPRYNG CONCURRENTLY WITH UPLINZA OR SOLIRIS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS WITH: (1) A DIAGNOSIS OF NEUROMYELITIS OPTICA SPECTRUM DISORDER AND (2) LABS DOCUMENTING POSITIVE ANTI-AQUAPORIN-4 ANTIBODIES, AND (3) FAILURE TO RESPOND TO TREATMENT WITH OR CONTRAINDICATION TO ORAL STEROIDS. RENEWAL CRITERIA: DOCUMENTATION OF (1) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) THE PATIENT HAS A CLINICALLY MEANINGFUL RESPONSE TO THERAPY AS DOCUMENTED BY THE PRESCRIBER.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH A SPECIALIST (FOR EXAMPLE NEUROLOGIST OR OPHTHALMOLOGIST).

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ENZYME REPLACEMENT

MEDICATION(S)
CERDELGA, CHOLBAM, NITISINONE, ORFADIN 4 MG/ML SUSPENSION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEMATOLOGY, HEPATOLOGY, AND NEPHROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

EPCLUSA

MEDICATION(S)
EPCLUSA 150-37.5 MG PELLET PKT, EPCLUSA 200 MG-50 MG TABLET, EPCLUSA 200-50 MG PELLET PACK, SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 3 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

COVERAGE DURATION
DURATION PER GENOTYPE AND DIAGNOSIS. 12 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ERYTHROPOIESIS STIMULATING AGENTS

MEDICATION(S)
ARANESP, RETACRIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR CANCER DIAGNOSIS: DOCUMENTED CHEMOTHERAPY-ASSOCIATED ANEMIA (HEMOGLOBIN LESS THAN 10G/DL OR HEMATOCRIT LESS THAN 30%).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

PART B PREREQUISITE
N/A

EUCRISA

MEDICATION(S)
EUCRISA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID, PIMECROLIMUS CREAM OR TACROLIMUS OINTMENT.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

EVRYSDI

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
THE PATIENT HAS NOT RECEIVED ZOLGENSMA OR CELL THERAPY. THE PATIENT WILL NOT BE USING SPINRAZA CONCURRENTLY WITH EVRYSDI AND THE LAST DOSE OF SPINRAZA (IF APPLICABLE) WILL BE AT LEAST 90 DAYS BEFORE THE INITIATION OF THERAPY WITH EVRYSDI. THE PATIENT MUST NOT BE DEPENDENT ON EITHER OF THE FOLLOWING: (1) INVASIVE VENTILATION OR TRACHEOSTOMY, OR (2) USE OF NON-INVASIVE VENTILATION BEYOND USE FOR NAPS AND NIGHTTIME SLEEP.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF SPINAL MUSCULAR ATROPHY (SMA), CONFIRMED BY GENETIC TESTING OF 5Q-AUTOSOMAL RECESSIVE SMA , AND (2) DOCUMENTATION OF BASELINE MOTOR FUNCTION BY ONE OF THE FOLLOWING EXAMS: (1) HAMMERSMITH INFANT NEUROLOGIC EXAM [HINE] (INFANT TO EARLY CHILDHOOD), (2) HAMMERSMITH FUNCTIONAL MOTOR SCALE EXPANDED [HFMSE], (3) UPPER LIMB MODULE [ULM] TEST (NON-AMBULATORY), OR (4) CHILDRENS HOSPITAL OF PHILADELPHIA INFANT TEST OF NEUROMUSCULAR DISORDERS [CHOP-INTEND]. RENEWAL CRITERIA: DOCUMENTATION OF CLINICALLY SIGNIFICANT IMPROVEMENT OF MOTOR FUNCTION AS DEMOSTRATED IN ONE OF THE FOLLOWING TESTS: (1) HINE: (A) IMPROVEMENT OR MAINTENANCE OF PREVIOUS IMPROVEMENT IN ONE OF THE FOLLOWING: (I) AT LEAST 2 POINT (OR MAXIMAL SCORE) INCREASE IN ABILITY TO KICK, OR (II) AT LEAST 1 POINT INCREASE IN ANY OTHER HINE MILESTONE (E.G. HEAD CONTROL, ROLLING, SITTING, CRAWLING, ETC) EXCLUDING VOLUNTARY GRASP, AND, (B) ONE OF THE FOLLOWING: (I) DEMONSTRATED IMPROVEMENT IN MORE CATEGORIES THAN WORSENING (EXCLUDING VOLUNTARY GRASP) FROM PRETREATMENT BASELINE, OR (II) ACHIEVEMENT OR MAINTENANCE OF ANY NEW MOTOR MILESTONES WHEN THEY WOULD OTHERWISE BE UNEXPECTED TO DO SO, OR (2) HFMSE: IMPROVEMENT OR MAINTENANCE OF PREVIOUS IMPROVEMENT IN ONE OF THE

FOLLOWING: (A) AT LEAST 3 POINT INCREASE IN SCORE FROM PRETREATMENT BASELINE, OR (B) ANY NEW MOTOR MILESTONES WHEN THEY WOULD OTHERWISE BE UNEXPECTED TO DO SO, OR (3) ULM: IMPROVEMENT OR MAINTENANCE OF PREVIOUS IMPROVEMENT IN ONE OF THE FOLLOWING: (A) AT LEAST 2 POINT INCREASE IN SCORE FROM PRETREATMENT BASELINE, OR, (B) ANY NEW MOTOR MILESTONES WHEN THEY WOULD OTHERWISE BE UNEXPECTED TO DO SO, OR (4) CHOP-INTEND: IMPROVEMENT OR MAINTENANCE OF PREVIOUS IMPROVEMENT IN ONE OF THE FOLLOWING: (A) AT LEAST 4 POINT INCREASE IN SCORE FROM PRETREATMENT BASELINE, OR (B) ANY NEW MOTOR MILESTONES WHEN THEY WOULD OTHERWISE BE UNEXPECTED TO DO SO.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 2 MONTHS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH NEUROLOGIST OR PEDIATRIC NEUROMUSCULAR SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. A CURRENT WEIGHT IS REQUIRED FOR ALL REQUESTS.

PART B PREREQUISITE
N/A

FDA-APPROVED INDICATIONS

MEDICATION(S)
AMIKACIN SULFATE, APOMORPHINE HCL, ARALAST NP, ARMODAFINIL, BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE, BERINERT, CASPOFUNGIN ACETATE, CAYSTON, COLISTIMETHATE, CORLANOR 5 MG/5 ML ORAL SOLN, CYCLOSERINE, DOJOLVI, ERAXIS, GLASSIA, HAEGARDA, ICATIBANT, INVEGA HAFYERA, IVABRADINE HCL, KALBITOR, LACRISERT, LANREOTIDE ACETATE, LUPRON DEPOT-PED, METYROSINE, MIFEPRISTONE 300 MG TABLET, MODAFINIL, MOUNJARO, NAYZILAM, NITAZOXANIDE, NUPLAZID, OXANDROLONE, OZEMPIC, OZEMPIC .25 OR 0.5 PEN INJCTR (DOSE 3 ML), OZEMPIC 0.25 OR .5 PEN INJCTR (DOSE 1.5 ML), PENTAMIDINE 300 MG INJECT VIAL, PERSERIS, PLERIXAFOR, PRETOMANID, PROLASTIN C, PROLIA, QUININE SULFATE, RUCONEST, RYBELSUS, SAJAZIR, SIRTURO, SODIUM PHENYLBUTYRATE 500MG TB, SOMATULINE DEPOT 60 MG/0.2 ML, SOMATULINE DEPOT 90 MG/0.3 ML, SOMAVERT, SYMPROIC, SYNAREL, TOBI PODHALER, TOBRAMYCIN SULFATE, TRULICITY, UZEDY, VALTOCO, VISTOGARD, ZEMAIRA, ZULRESSO, ZURZUVAE, ZYPREXA RELPREVV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

FDA-APPROVED INDICATIONS - DOSE LIMIT

MEDICATION(S)
EPIDIOLEX, ILARIS, TAKHZYRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

FDA-APPROVED INDICATIONS WITH BVD

MEDICATION(S)
ABELCET, AMPHOTERICIN B, AMPHOTERICIN B LIPOSOME, ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, DRONABINOL, FLEBOGAMMA DIF, GAMASTAN, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

PART B PREREQUISITE
N/A

FENFLURAMINE

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR LENNOX-GASTAUT SYNDROME (LGS), DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO OTHER SEIZURE MEDICATIONS SUCH AS FELBAMATE, LAMOTRIGINE, TOPIRAMATE, CLOBAZAM, OR RUFINAMIDE. RENEWAL CRITERIA: FOR DRAVET SYNDROME, DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

FORTEO

MEDICATION(S)
FORTEO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF: (A) FRAGILITY FRACTURE OF THE SPINE OR HIP WITHIN THE LAST FIVE YEARS, OR (B) SEVERE OSTEOPOROSIS WITH A T-SCORE OF SPINE, HIP OR FEMORAL NECK OF MINUS 3.5 OR LOWER, OR (C) OSTEOPOROSIS WITH A T-SCORE OF MINUS 2.5 OR LOWER AND (I) INTOLERANCE OR CONTRAINDICATION TO BISPHOSPHONATE THERAPY, OR (II) PROGRESSIVE BONE LOSS DEFINED AS BONE LOSS OF THREE PERCENT OR HIGHER DESPITE THERAPY WITH BISPHOSPHONATES, AND (2) DOCUMENTED FAILURE OF, INTOLERANCE TO, OR CONTRAINDICATIONS TO TYMLOS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
LIMITED TO 2 YEARS UNLESS THE PATIENT REMAINS AT OR HAS RETURNED TO HAVING A HIGH RISK FOR FRACTURE.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GALAFOLD

MEDICATION(S)
GALAFOLD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEMATOLOGY, AND NEPHROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) TREATMENT OF PATIENTS WITH SHORT BOWEL SYNDROME, AND (2) WHO HAVE BEEN DEPENDENT ON PARENTERAL (OR A COMBINATION OF PARENTERAL AND ENTERAL) NUTRITION FOR ALL NUTRITIONAL REQUIREMENTS FOR AT LEAST ONE YEAR, AND (3) IN WHOM A TAPER FROM PARENTERAL REQUIREMENTS HAS NOT BEEN POSSIBLE OR PLANNED. RENEWAL CRITERIA: MEDICAL RECORD DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
DOSE IS LIMITED TO THE FDA-APPROVED DOSE OF 0.05 MG/KG PER DAY.

PART B PREREQUISITE
N/A

GIMOTI

MEDICATION(S)
GIMOTI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO PREFERRED MEDICATIONS: (1) METOCLOPRAMIDE TABLETS OR SOLUTION AND (2) METOCLOPRAMIDE ODT TABLETS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HADLIMA

MEDICATION(S)
HADLIMA, HADLIMA PUSHTOUCH, HADLIMA(CF), HADLIMA(CF) PUSHTOUCH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE HADLIMA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) RHEUMATOID ARTHRITIS WITH: (I) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH HIGH DISEASE ACTIVITY AND POOR PROGNOSIS, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS OR PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (4) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (5) CROHN'S DISEASE WITH: (I) FISTULIZING OR SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPURINE, OR METHOTREXATE FOR 3 MONTHS, OR (6) ULCERATIVE COLITIS WITH: (I) SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO

ONE OF THE FOLLOWING FOR 3 MONTHS: SULFASALAZINE, MESALAMINE, BALSALAZIDE, PREDNISONE, BUDESONIDE, AZATHIOPRINE, 6-MERCAPTOPURINE, OR (7) HIDRADENITIS SUPPURATIVA, OR (8) NON-INFECTIOUS INTERMEDIATE, POSTERIOR AND PANUVEITIS. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, GASTROENTEROLOGIST, OPHTHALMOLOGIST, OR RHEUMATOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

HARVONI

MEDICATION(S)
HARVONI 33.75-150 MG PELLET PK, HARVONI 45-200 MG PELLET PACKT, HARVONI 45-200 MG TABLET, LEDIPASVIR-SOFOSBUVIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 3 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

COVERAGE DURATION
12-24 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES. 8 WK APPROVALS PER PROVIDER REQUEST.

OTHER CRITERIA
DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF ONE TABLET DAILY.

PART B PREREQUISITE
N/A

HIGH-STRENGTH OPIOID AGENTS

MEDICATION(S)
BUPRENORPHINE, FENTANYL 100 MCG/HR PATCH, FENTANYL 12 MCG/HR PATCH, FENTANYL 25 MCG/HR PATCH, FENTANYL 50 MCG/HR PATCH, FENTANYL 75 MCG/HR PATCH, METHADONE 10 MG/5 ML SOLUTION, METHADONE 10 MG/ML ORAL CONC, METHADONE 5 MG/5 ML SOLUTION, METHADONE HCL 10 MG TABLET, METHADONE HCL 5 MG TABLET, METHADONE INTENSOL, MORPHINE SULF ER 15 MG TABLET, MORPHINE SULF ER 30 MG TABLET, MORPHINE SULF ER 60 MG TABLET, OXYCODONE HCL (IR) 30 MG TAB, OXYCODONE HCL ER, OXYCONTIN, TRAMADOL HCL-ACETAMINOPHEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PROVIDER ATTESTATION OF INTENT TO MONITOR FOR SIDE EFFECTS AND APPROPRIATE USE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS

MEDICATION(S)
JUXTAPID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL: (1) CONFIRMED DIAGNOSIS OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA, AND (2) THERAPEUTIC FAILURE, INTOLERANCE, OR CONTRAINDICATION TO ONE HIGH-INTENSITY STATIN THERAPY AND TO ONE PCSK9-INHIBITOR (SUCH AS REPATHA).
RENEWAL: DOCUMENTATION OF BENEFICIAL RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY CARDIOLOGY, ENDOCRINOLOGY, LIPIDOLOGY OR IN CONSULTATION WITH THESE SPECIALISTS.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HUMIRA

MEDICATION(S)
HUMIRA, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE HUMIRA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) RHEUMATOID ARTHRITIS WITH: (I) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH HIGH DISEASE ACTIVITY AND POOR PROGNOSIS, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS OR PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (4) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (5) CROHN'S DISEASE WITH: (I) FISTULIZING OR SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPURINE, OR

METHOTREXATE FOR 3 MONTHS, OR (6) ULCERATIVE COLITIS WITH: (I) SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: SULFASALAZINE, MESALAMINE, BALSALAZIDE, PREDNISONE, BUDESONIDE, AZATHIOPRINE, 6-MERCAPTOPURINE, OR (7) HIDRADENITIS SUPPURATIVA, OR (8) NON-INFECTIOUS INTERMEDIATE, POSTERIOR AND PANUVEITIS. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, GASTROENTEROLOGIST, OPHTHALMOLOGIST, OR RHEUMATOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

IDIOPATHIC PULMONARY FIBROSIS AGENTS

MEDICATION(S)
OFEV, PIRFENIDONE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR OFEV, FOR THE DIAGNOSIS OF SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD), DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ACTEMRA SUBCUTANEOUS. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PULMONOLOGY

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES

PART B PREREQUISITE
N/A

INBRIJA

MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE INBRIJA CONCURRENTLY WITH APOMORPHINE.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS: (1) WITH A DIAGNOSIS OF PARKINSON'S DISEASE WITH OFF EPISODES, (2) WITH A PROVIDER ATTESTATION THAT PATIENT HAS OR WILL RECEIVE EDUCATION ON PROPER INHALER TECHNIQUE, (3) WHO ARE TAKING CARBIDOPA/LEVODOPA, (4) WHO HAVE TRIED AND FAILED AT LEAST ONE OF THE FOLLOWING AGENTS FOR AT LEAST 4 WEEKS IN COMBINATION WITH CARBIDOPA/LEVODOPA TO REDUCE THE NUMBER AND FREQUENCY OF OFF EPISODES: (A) RASAGILINE, (B) ROPINIROLE, (C) ENTACAPONE, (D) PRAMIPEXOLE, (E) ROTIGOTINE, OR (F) SELEGILINE, AND (5) PATIENT HAS (A) NO UNDERLYING LUNG DISEASE, OR (B) LIMITED PULMONARY FUNCTION (FEV LESS THAN 50%) WITH A PROVIDER ATTESTATION ACKNOWLEDGING INBRIJA HAS NOT BEEN STUDIED IN THIS POPULATION AND DRUG MAY BE INEFFECTIVE DUE TO LACK OF INSPIRATORY CAPACITY, AND PROVIDER ATTESTS POTENTIAL BENEFITS OUTWEIGH RISKS. RENEWAL CRITERIA: PROVIDER DOCUMENTATION OF IMPROVEMENT IN OFF PERIOD SYMPTOMS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH NEUROLOGY.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

INFECTIOUS DISEASE SELECT AGENTS

MEDICATION(S)
LINEZOLID, LINEZOLID-0.9% NACL, LINEZOLID-D5W, POSACONAZOLE DR 100 MG TABLET, VORICONAZOLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE, TRANSPLANT, HEMATOLOGY OR ONCOLOGY SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INGREZZA

MEDICATION(S)
INGREZZA, INGREZZA INITIATION PK(TARDIV), INGREZZA SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ISAVUCONAZONIUM

MEDICATION(S)
CRESEMBA 186 MG CAPSULE, CRESEMBA 74.5 MG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) (A) FOR INVASIVE ASPERGILLOSIS, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO VORICONAZOLE AND POSACONAZOLE, OR (B) FOR INVASIVE MUCORMYCOSIS, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO POSACONAZOLE. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE, TRANSPLANT, HEMATOLOGY OR ONCOLOGY SPECIALIST.

COVERAGE DURATION
THREE MONTHS, THEN SIX MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ISTURISA

MEDICATION(S)
ISTURISA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENTS WITH CUSHINGS DISEASE, AND (2) PATIENTS FOR WHOM PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE, AND (3) THE PATIENT HAS TRIED AND FAILED, IS UNABLE TO TOLERATE OR HAS CONTRAINDICATIONS TO AT LEAST TWO OF THE FOLLOWING: KETOCONAZOLE, CABERGOLINE OR PASIREOTIDE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION OF CLINICAL IMPROVEMENT (REDUCTION IN 24-HOUR URINARY FREE CORTISOL).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ITRACONAZOLE

MEDICATION(S)
ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG/10 ML CUP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KALYDECO

MEDICATION(S)
KALYDECO, ORKAMBI, SYMDEKO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF EFFECTIVENESS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A SPECIALIST FROM A CYSTIC FIBROSIS TREATMENT CENTER OR A PULMONOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

KERENDIA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITOR (FOR EXAMPLE, JARDIANCE, SYNJARDY, ETC).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KINERET

MEDICATION(S)
KINERET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE KINERET CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS), INCLUDING FAMILIAL COLD AUTO-INFLAMMATORY SYNDROMES (FCAS), MUCKLE-WELLS SYNDROME (MWS) AND NEONATAL-ONSET MULTISYSTEM INFLAMMATORY DISEASE (NOMID), OR (2) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (3) DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) WITH GENETIC TESTING CONFIRMING MUTATION IN THE IL1RN GENE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, PEDIATRICS (FOR CHILDREN WITH CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES), GENETICS, A DERMATOLOGY SPECIALIST OR A PHYSICIAN SPECIALIZING IN THE TREATMENT OF AUTOINFLAMMATORY DISORDERS.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

KISQALI

MEDICATION(S)
KISQALI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST ONE PREFERRED DRUG. PREFERRED DRUGS INCLUDE: VERZENIO OR IBRANCE. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5% PATCH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LOTRONEX

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF EFFECTIVENESS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MAVENCLAD

MEDICATION(S)
MAVENCLAD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE MAVENCLAD CONCURRENTLY WITH OTHER MULTIPLE SCLEROSIS DISEASE MODIFYING DRUGS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PRESCRIBED FOR PATIENTS WITH FDA-APPROVED INDICATIONS, AND (2) PATIENT HAS NOT ACHIEVED SUSTAINED REMISSION AFTER TREATMENT WITH AT LEAST TWO PRIOR DISEASE MODIFYING THERAPIES (EXAMPLES GILENYA, DIMETHYL FUMARATE, PLEGRIDY, AVONEX, ETC.), AND (3) PATIENT HAS NOT PREVIOUSLY COMPLETED TWO ANNUAL TREATMENT COURSES (A TOTAL OF FOUR TREATMENT CYCLES) WITH MAVENCLAD. RENEWAL CRITERIA: (1) PATIENT HAS EXPERIENCED BENEFIT FROM THERAPY DEMONSTRATED BY REDUCTION IN SYMPTOMS, DISEASE PROGRESSION OR A REDUCTION IN RELAPSE FREQUENCY, AND (2) PATIENT HAS NOT ALREADY COMPLETED TWO ANNUAL TREATMENT COURSES (A TOTAL OF FOUR TREATMENT CYCLES) WITH MAVENCLAD.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH NEUROLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

MAVYRET

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

COVERAGE DURATION
8-16 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES. 8 WK APPROVALS PER PROVIDER REQUEST.

OTHER CRITERIA
DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF THREE TABLETS DAILY.

PART B PREREQUISITE
N/A

MECASERMIN

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

METABOLIC DISORDER AGENTS

MEDICATION(S)
CARGLUMIC ACID, JAVYGTOR, RAVICTI, SAPROPTERIN DIHYDROCHLORIDE, SUCRAID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

MYFEMBREE

MEDICATION(S)
MYFEMBREE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS WITH: (1) A DIAGNOSIS OF HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS (FIBROIDS) IN PREMENOPAUSAL WOMEN, AND THE PATIENT HAS TRIED AND FAILED OR HAS CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING: (A) PREFERRED CONTRACEPTIVE PREPARATION (FOR EXAMPLE, ORAL CONTRACEPTIVE OR VAGINAL CONTRACEPTIVE), (B) LEVONORGESTREL INTRA-UTERINE DEVICE (IUD), OR (C) ORAL TRANEXAMIC ACID, OR (2) A DIAGNOSIS OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS, AND PATIENT HAS A DOCUMENTED INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO (A) PRESCRIPTION STRENGTH NSAID, AND (B) CONTINUOUS ORAL CONTRACEPTIVE THERAPY OR PROGESTERONE THERAPY. RENEWAL CRITERIA: PHYSICIAN ATTESTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN OB/GYN SPECIALIST.

COVERAGE DURATION
SIX MONTHS, THEN 18 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

NARCOTIC AGENTS

MEDICATION(S)
FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH ORAL NARCOTIC TABLETS, CAPSULES, OR LIQUID.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

PART B PREREQUISITE
N/A

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) HISTORY OF HYPOPARATHYROIDISM FOR AT LEAST 18 MONTHS, AND (3) SERUM MAGNESIUM LEVEL WITHIN LABORATORY NORMAL LIMITS, AND (4) UPON INITIATION OF NATPARA THERAPY, NATPARA TO BE USED AS AN ADJUNCT TO CALCITRIOL AT LEAST 0.25 MCG/DAY. RENEWAL CRITERIA: SERUM CALCIUM CONCENTRATION MUST BE MAINTAINED IN THE LOWER HALF OF LABORATORY NORMAL REFERENCE RANGE.

AGE RESTRICTION
LIMITED TO ADULTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
ALL FDA-LABELED DOSAGE AND ADMINISTRATION GUIDELINES MUST BE MET.

PART B PREREQUISITE
N/A

NORTHERA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF CONTRAINDICATIONS OR TRIAL AND FAILURE OF AT LEAST TWO FIRST LINE DRUG THERAPIES (FOR EXAMPLE FLUDROCORTISONE AND MIDODRINE). RENEWAL CRITERIA: MEDICAL RECORD DOCUMENTATION OF CONTINUED EFFECTIVENESS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR NEUROLOGIST.

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NOURIANZ

MEDICATION(S)
NOURIANZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF PARKINSONS DISEASE WITH AT LEAST 2 HOURS OF OFF EPISODES PER DAY, AND (2) PATIENT IS CURRENTLY TAKING CARBIDOPA/LEVODOPA, AND (3) PATIENT HAS TRIED AND FAILED AT LEAST ONE OF THE FOLLOWING AGENTS FOR AT LEAST 4 WEEKS IN COMBINATION WITH CARBIDOPA/LEVODOPA TO REDUCE THE NUMBER AND FREQUENCY OF OFF EPISODES: (A) RASAGILINE, (B) ROPINIROLE, (C) ENTACAPONE, (D) PRAMIPEXOLE, (E) ROTIGOTINE, OR (F) SELEGILINE . RENEWAL CRITERIA: PROVIDER DOCUMENTATION OF IMPROVEMENT IN OFF PERIOD SYMPTOMS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH NEUROLOGY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

NUCALA

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE NUCALA CONCURRENTLY WITH ANOTHER BIOLOGIC THERAPY FOR THE TREATMENT OF ASTHMA SUCH AS CINQAIR, DUPIXENT, FASENRA OR XOLAIR.

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. FOR SEVERE ASTHMA: INITIAL CRITERIA: (1) FOR PATIENTS DIAGNOSED WITH ASTHMA THEY HAVE A PRE-TREATMENT SERUM EOSINOPHIL COUNT OF 150 CELLS/MCL OR GREATER AT SCREENING (WITHIN THE PREVIOUS 12 MONTHS), AND (2) PATIENT HAS INADEQUATE ASTHMA CONTROL DESPITE USE OF AN INHALED STEROID (SUCH AS FLUTICASONE PROPIONATE HFA), AND AT LEAST ONE OTHER MAINTENANCE MEDICATION: (A) LEUKOTRIENE RECEPTOR ANTAGONIST, (B) LONG-ACTING BETA-AGONIST (SUCH AS SEREVENT), (C) LONG-ACTING MUSCARINIC ANTAGONIST (SUCH AS INCRUSE ELLIPTA), OR (D) THEOPHYLLINE, AND (3) INADEQUATE ASTHMA CONTROL DESPITE STANDARD THERAPIES IS DEFINED AS ONE OF THE FOLLOWING: (A) AT LEAST ONE EXACERBATION REQUIRING ORAL SYSTEMIC CORTICOSTEROIDS IN THE LAST 12 MONTHS, OR (B) AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT IN THE LAST 12 MONTHS. FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS: APPROVE. FOR HYPEREOSINOPHILIC SYNDROME: APPROVE. FOR CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: (1) PATIENT IS CURRENTLY RECEIVING THERAPY WITH AN INTRANASAL CORTICOSTEROID OR HAS TRIED AND FAILED OR HAS A MEDICAL CONTRAINDICATION TO INTRANASAL CORTICOSTEROIDS. RENEWAL CRITERIA: (1) FOR NASAL POLYPS, DOCUMENTATION OF POSITIVE RESPONSE. (2) FOR ASTHMA, (A) CONTINUED USE OF AN INHALED STEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, (B) PATIENT HAS A POSITIVE RESPONSE AS DEFINED BY ONE OF THE FOLLOWING: (I) DECREASED FREQUENCY OF EXACERBATIONS (II) DECREASED USE OF RESCUE MEDICATIONS, (III)

REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (IV) IMPROVEMENT IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH AN ASTHMA SPECIALIST, ALLERGIST, PULMONOLOGIST, HEMATOLOGIST, OTOLARYNGOLOGIST OR RHEUMATOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

PART B PREREQUISITE
N/A

NURTEC ODT

MEDICATION(S)
NURTEC ODT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH OTHER CGRP ANTAGONISTS FOR MIGRAINE PREVENTION (SUCH AS AJOVY).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF ACUTE MIGRAINE (WITH OR WITHOUT AURA), AND A DOCUMENTED INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST ONE TRIPTAN DRUG (EXAMPLES SUMATRIPTAN, NARATRIPTAN, RIZATRIPTAN) OR (2) DIAGNOSIS OF EPISODIC MIGRAINE PREVENTION AND MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO AT LEAST ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

NUZYRA

MEDICATION(S)
NUZYRA 150 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) RESERVED FOR PATIENTS WITH: (A) DIAGNOSIS OF COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA WITH AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A QUINOLONE SUCH AS LEVOFLOXACIN OR MOXIFLOXACIN, OR (B) DIAGNOSIS OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS WITH AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO LINEZOLID, AND (2) CULTURE AND SENSITIVITY INFORMATION INDICATES BACTERIA ARE SUSCEPTIBLE TO NUZYRA.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.

COVERAGE DURATION
14 DAYS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS (1) WITH A DIAGNOSIS OF PRIMARY BILIARY CHOLANGITIS AND (2) WHO (A) HAVE FAILED TO ACHIEVE AN AKLALINE PHOSPHATASE (ALP) LEVEL OF LESS THAN 1.67 TIMES THE UPPER LIMIT OF NORMAL AFTER AT LEAST 12 MONTHS OF TREATMENT WITH URSODEOXYCHOLIC ACID (UDCA) OR (B) HAVE A HISTORY OF CONTRAINDICATION OR INTOLERANCE TO UDCA. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY OR HEPATOLOGY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. MUST BE USED IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) UNLESS UDCA IS CONTRAINDICATED OR NOT TOLERATED.

PART B PREREQUISITE
N/A

ORAL DISSOLVE TABLETS PROTECTED CLASS

MEDICATION(S)
ARIPIPRAZOLE ODT, CLOZAPINE ODT, RISPERIDONE ODT, SPRITAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH OR CONTRAINDICATION TO ONE REGULAR TABLET DOSAGE FORM OF THE REQUESTED MEDICATION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ORAL LIQUID PROTECTED CLASS

MEDICATION(S)
CHLORPROMAZINE 100 MG/ML CONC, CHLORPROMAZINE 30 MG/ML CONC, EPRONTIA, VERSACLOZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH REGULAR TABLET OR CAPSULE DOSAGE FORMS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ORAL ONCOLOGY AGENTS

MEDICATION(S)

AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AYVAKIT, BALVERSA, BEXAROTENE, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE 100 MG TABLET, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DASATINIB, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, EXKIVITY, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GLEOSTINE, IBRANCE, ICLUSIG, IDHIFA, IMBRUVICA 140 MG CAPSULE, IMBRUVICA 420 MG TABLET, IMBRUVICA 560 MG TABLET, IMBRUVICA 70 MG/ML SUSPENSION, INLYTA, INQOVI, INREBIC, ITOVEBI, IWILFIN, JAKAFI, JAYPIRCA, KISQALI FEMARA CO-PACK, KOSELUGO, KRAZATI, LAPATINIB, LAZCLUZE, LENVIMA, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYTGOBI, MATULANE, MEKINIST, MEKTOVI, NERLYNX, NILUTAMIDE, NINLARO, NUBEQA, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, ORGOVYX, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY, POMALYST, POTASSIUM CL ER 20 MEQ TABLET (DISSOLVABLE TABLET), QINLOCK, RETEVMO, REZLIDHIA, REZUROCK, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB, STIVARGA, SUNITINIB MALATE, SYNRIBO, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, TIBSOVO, TOREMIFENE CITRATE, TORPENZ, TRUQAP, TUKYSA, TURALIO, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, WELIREG, XALKORI, XOSPATA, XPOVIO, XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA:

DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ORENCIA

MEDICATION(S)
ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ORENCIA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HADLIMA, AND HUMIRA, OR (2) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, STELARA, TREMFYA, RINVOQ, SKYRIZI AND COSENTYX, OR (3) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (4) PROPHYLAXIS OF ACUTE GRAFT VERSUS HOST DISEASE AND UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) FROM A MATCHED OR ONE ALLELE-MISMATCHED UNRELATED-DONOR, IN COMBINATION WITH A CALCINEURIN INHIBITOR (EXAMPLE CYCLOSPORINE, TACROLIMUS, PIMECROLIMUS) AND METHOTREXATE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST OR TRANSPLANT SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ORIAHNN

MEDICATION(S)
ORIAHNN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS WITH: (1) A DIAGNOSIS OF HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS (FIBROIDS) IN PREMENOPAUSAL WOMEN, AND (2) THE PATIENT HAS TRIED AND FAILED OR HAS CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING: (A) PREFERRED CONTRACEPTIVE PREPARATIONS (FOR EXAMPLE, ORAL OR VAGINAL CONTRACEPTIVES), OR (B) LEVONORGESTREL INTRA-UTERINE DEVICE (IUD), OR (C) ORAL TRANEXAMIC ACID, AND (3) SURGICAL INTERVENTION HAS BEEN DISCUSSED AND IS NOT AN APPROPRIATE TREATMENT OPTION OR PATIENT DECLINES. RENEWAL CRITERIA: PHYSICIAN ATTESTATION OF IMPROVEMENT OF HEAVY MNSTRUAL BLEEDING.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH A OB/GYN SPECIALIST.

COVERAGE DURATION
SIX MONTHS, THEN 18 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

ORILISSA

MEDICATION(S)
ORILISSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS A DOCUMENTED INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO (A) PRESCRIPTION STRENGTH NSAID, AND (B) CONTINUOUS ORAL CONTRACEPTIVE THERAPY OR PROGESTERONE THERAPY.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH OBSTETRICS/GYNECOLOGY.

COVERAGE DURATION
SIX MONTHS, THEN SIX MONTHS IF POSITIVE RESPONSE, LIMITED TO A MAX LIFETIME DURATION OF 24 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN FDA-APPROVED LABELING, INCLUDING APPROPRIATE LIMITS ON TOTAL DURATION OF THERAPY.

PART B PREREQUISITE
N/A

ORLADEYO

MEDICATION(S)
ORLADEYO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ORLADEYO CONCURRENTLY WITH OTHER BIOLOGIC PROPHYLACTIC THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: RESERVED FOR PATIENTS WHO HAVE (1) A DIAGNOSIS OF HEREDITARY ANGIOEDEMA (HAE), AND (2) DOCUMENTATION OF FAILURE OR MEDICAL CONTRAINDICATION TO TAKHZYRO, AND (3) DOCUMENTATION OF A HAE MANAGEMENT PLAN AND USE OF THIS THERAPY IS IN ACCORDANCE WITH THAT PLAN. RENEWAL CRITERIA: (1) MEDICAL CHART DOCUMENTATION OF THE NUMBER AND SEVERITY OF HAE ATTACKS OCCURRING IN THE PREVIOUS 6 MONTHS, AND (2) PATIENT HAS EXPERIENCED A REDUCTION IN THE NUMBER OF HAE ATTACKS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A HEMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.

COVERAGE DURATION
SIX MONTHS, THEN EVERY SIX MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

OTEZLA

MEDICATION(S)
OTEZLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE OTEZLA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, STELARA, TREMFYA, RINVOQ, SKYRIZI AND COSENTYX, OR (2) MODERATE TO SEVERE PLAQUE PSORIASIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, COSENTYX, STELARA, TREMFYA AND SKYRIZI, OR (3) DIAGNOSIS OF ORAL ULCERS ASSOCIATED WITH BEHCET DISEASE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

PARICALCITOL

MEDICATION(S)
PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH CALCITRIOL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

PART B PREREQUISITE
N/A

PART D VS PART B

MEDICATION(S)

ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR SODIUM, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 25 MG/5 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL 75 MG/15 ML SOLN, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMINOSYN II 10% IV SOLUTION, AMINOSYN II 7% IV SOLUTION, AMINOSYN II 8.5% IV SOLUTION, AMINOSYN II WITH ELECTROLYTES, AMINOSYN M, AMINOSYN 8.5%-ELECTROLYTES SOL, AMINOSYN-PF, APREPITANT, AZATHIOPRINE, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CLINISOL, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE 250 MG/5 ML AMPUL, CYCLOSPORINE MODIFIED, EMEND 125 MG POWDER PACKET, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENVARSUS XR, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPARIN 20,000 UNIT/500 ML-D5W, HEPLISAV-B, IMOVAX RABIES VACCINE, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, METHOTREXATE, METHOTREXATE SODIUM, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, MYHIBBIN, ONDANSETRON 4 MG/5 ML SOLN CUP, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT 4 MG TABLET, ONDANSETRON ODT 8 MG TABLET, PENTAMIDINE 300 MG INHAL POWDR, PREDNISOLONE 15 MG/5 ML SOLN, PREDNISOLONE 15MG/5ML SOLN CUP, PREDNISOLONE 10 MG/5 ML SOLN, PREDNISOLONE 15 MG/5 ML SOLN, PREDNISOLONE 15MG/5ML SOLN CUP, PREDNISOLONE 20 MG/5 ML SOLN, PREDNISOLONE 5 MG/5 ML SOLN, PREDNISOLONE SOD PH 25 MG/5 ML, PREDNISONE 1 MG TABLET, PREDNISONE 10 MG TABLET, PREDNISONE 2.5 MG TABLET, PREDNISONE 20 MG TABLET, PREDNISONE 5 MG TABLET, PREDNISONE 5 MG/5 ML SOLUTION, PREDNISONE 50 MG TABLET, PREDNISONE INTENSOL, PREHEVBRIO, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROSOL, PULMOZYME, RABAVERT, RECOMBIVAX HB, RIBAVIRIN 6 GM INHALATION VIAL, SIROLIMUS, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TOBRAMYCIN PAK 300 MG/5 ML, VENTAVIS

DETAILS

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

PEGASYS

MEDICATION(S)
PEGASYS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR TREATMENT OF HEPATITIS C, DOCUMENTATION OF HCV GENOTYPE, VIRAL LOAD AND LIVER FUNCTION TESTS, AND DOCUMENTATION OF INTOLERANCE TO OR ADVERSE EFFECTS FROM PRIOR USE OF PEGINTRON.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, OR HEPATOLOGY, OR INFECTIOUS DISEASE SPECIALISTS.

COVERAGE DURATION
12-48 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES FOR PATIENT DIAGNOSIS AND GENOTYPE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE.

PART B PREREQUISITE
N/A

PENICILLAMINE

MEDICATION(S)
D-PENAMINE, PENICILLAMINE 250 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF (1) HOMOZYGOUS CYSTINURIA AND URINARY CYSTINE GREATER THAN 500MG/DAY AFTER TREATMENT WITH POTASSIUM CITRATE AND CAPTOPRIL, OR MEDICAL DOCUMENTATION FOR CONTRAINDICATION TO THEIR USE, OR (2) WILSON'S DISEASE. RENEWAL CRITERIA: DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 12 MONTHS AND POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH HEPATOLOGY, NEPHROLOGY OR RHEUMATOLOGY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

PHENOXYBENZAMINE

MEDICATION(S)
PHENOXYBENZAMINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE GENERIC ALPHA-BLOCKER, SUCH AS TERAZOSIN OR DOXAZOSIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY HEMATOLOGY, INFECTIOUS DISEASE AND HEPATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PULMONARY ARTERIAL HYPERTENSION - ORAL PREFERRED

MEDICATION(S)
ADEMPAS, AMBRISENTAN, BOSENTAN, OPSUMIT, TRACLEER 32 MG TABLET FOR SUSP, UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 200-800 TITRATION PACK, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS A DIAGNOSIS OF GROUP 1 PULMONARY HYPERTENSION AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION WITH THE FOLLOWING RESULTS: (A) MEAN PULMONARY ARTERIAL PRESSURE OF EQUAL TO OR GREATER THAN 20 MMHG AND (B) PULMONARY CAPILLARY WEDGE PRESSURE OF EQUAL TO OR LOWER THAN 15 MMHG AND (C) PULMONARY VASCULAR RESISTANCE OF EQUAL TO OR GREATER THAN 3 WOOD UNITS, AND (3) A NEGATIVE RESPONSE TO ACUTE PULMONARY VASODILATOR TESTING OR A TRIAL AND FAILURE OR CONTRAINDICATION TO CALCIUM CHANNEL BLOCKER THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

PYRUKYND

MEDICATION(S)
PYRUKYND

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF HEMOLYTIC ANEMIA WITH PYRUVATE KINASE (PK) DEFICIENCY. RENEWAL CRITERIA: DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 12 MONTHS AND CLINICALLY MEANINGFUL RESPONSE TO THERAPY AS DEFINED BY HEMOGLOBIN AND HEMOLYSIS LABORATORY RESULTS AND TRANSFUSION REQUIREMENTS.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

RADICAVA

MEDICATION(S)
RADICAVA ORS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF DEFINITE OR PROBABLE AMYOTROPHIC LATERAL SCLEROSIS (ALS) PER EL ESCORIAL/REVISED AIRLIE HOUSE CRITERIA OR AWAJI-SHIMA CRITERIA, AND (2) SCORE OF 2 OR MORE POINTS ON EACH SINGLE ITEM OF THE MOST RECENT ALS FUNCTIONAL RATING SCALE-REVISED (ALSFRS-R) SCORE, AND (3) ONSET OF ALS HAS BEEN LESS THAN 2 YEARS, AND (4) PERCENT FORCED VITAL CAPACITY (%FVC) IS GREATER THAN OR EQUAL TO 80% AT BASELINE, AND (5) JAPAN ALS SEVERITY CLASSIFICATION GRADE LESS THAN 3, AND (6) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO RILUZOLE. RENEWAL CRITERIA: REAUTHORIZATION WILL BE PROVIDED WHEN PATIENTS CONTINUE TO MEET CRITERIA 1 ABOVE, RADICAVA ORS IS PRESCRIBED BY A NEUROLOGIST AND IS LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY NEUROLOGY.

COVERAGE DURATION
SIX MONTHS, THEN EVERY SIX MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

RASUVO

MEDICATION(S)
RASUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
RESERVED FOR PATIENTS WHO HAVE: (1) LACK OF RESPONSE TO GENERIC METHOTREXATE INJECTION, OR (2) INTOLERANCE OR SIGNIFICANT ADVERSE EFFECTS FROM GENERIC METHOTREXATE INJECTION, OR (3) DEXTERITY CONCERNS, OR (4) VISUAL ACUITY CONCERNS, OR (5) IMPAIRED COGNITION PREVENTING SAFE USE OF GENERIC METHOTREXATE INJECTION, OR (6) MEDICAL CHART DOCUMENTATION OF NEEDLE PHOBIA PREVENTING USE OF GENERIC METHOTREXATE INJECTION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

REDITREX

MEDICATION(S)
REDITREX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
RESERVED FOR PATIENTS WHO HAVE: (1) LACK OF RESPONSE TO GENERIC METHOTREXATE INJECTION, OR (2) INTOLERANCE OR SIGNIFICANT ADVERSE EFFECTS FROM GENERIC METHOTREXATE INJECTION, OR (3) DEXTERITY CONCERNS, OR (4) VISUAL ACUITY CONCERNS, OR (5) IMPAIRED COGNITION PREVENTING SAFE USE OF GENERIC METHOTREXATE INJECTION, OR (6) MEDICAL CHART DOCUMENTATION OF NEEDLE PHOBIA PREVENTING USE OF GENERIC METHOTREXATE INJECTION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

REVCOVI

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF SEVERE COMBINED IMMUNODEFICIENCY DISEASE (SCID), AND (2) PATIENT HAS DEFICIENCY OF ADENOSINE DEAMINASE (ADA) CONFIRMED BY ONE OF THE FOLLOWING: (A) DECREASE IN ADENOSINE TRIPHOSPHATE (ATP) CONCENTRATION IN ERYTHROCYTES, OR, (B) MUTATION IN BOTH ALLELES OF THE ADA1 GENE, OR, (C) DEFICIENCY OR ABSENCE OF ADA IN FIBROBLASTS, ERYTHROCYTES OR PLASMA, OR, (D) POSITIVE SCREENING FOR T CELL RECEPTOR EXCISION CIRCLES (TRECS), AND (3) PATIENT IS NOT A CANDIDATE OR HAS FAILED A PRIOR HEMATOPOIETIC STEM CELL TRANSPLANT. RENEWAL CRITERIA: (1) ANNUAL REAUTHORIZATIONS WILL REQUIRE MEDICAL CHART DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) PROVIDER ATTESTS PATIENT IS UNABLE TO RECEIVE OR HAS FAILED A PRIOR HEMATOPOIETIC STEM CELL TRANSPLANT.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH A SPECIALIST

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

RINVOQ

MEDICATION(S)
RINVOQ, RINVOQ LQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE RINVOQ ER CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) RHEUMATOID ARTHRITIS WITH: (I) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH HIGH DISEASE ACTIVITY AND POOR PROGNOSIS, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH: (1) ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, AND (2) ONE OR MORE OF THE FOLLOWING: HUMIRA, HADLIMA, OR ENBREL, OR (2) PSORIATIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO: (1) ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, AND (2) ONE OR MORE OF THE FOLLOWING: HUMIRA, HADLIMA, OR ENBREL, OR (3) ATOPIC DERMATITIS WITH: (I) MEDICAL CHART DOCUMENTATION OF MODERATE TO SEVERE ATOPIC DERMATITIS WITH AT LEAST 10% BODY SURFACE AREA (BSA) OR INVOLVEMENT WITH THE FACE, NECK, HANDS, FEET, OR GENITALS, AND (II) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID OR ONE TOPICAL CALCINEURIN INHIBITOR (SUCH AS TACROLIMUS, PIMECROLIMUS), OR (4) ULCERATIVE COLITIS WITH: (I) SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO: (1) ONE OF THE FOLLOWING FOR 3 MONTHS: SULFASALAZINE, MESALAMINE, BALSALAZIDE, PREDNISONE, BUDESONIDE, AZATHIOPRINE, 6-MERCAPTOPURINE, AND (2) ONE OF THE FOLLOWING: HUMIRA OR HADLIMA, OR (5) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO: (1) TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL

CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, AND (2) ONE OR MORE OF THE FOLLOWING: HUMIRA, HADLIMA, OR ENBREL, OR (6) DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS WITH SIGNS OF INFLAMMATION AND DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, DERMATOLOGIST, GASTROENTEROLOGIST, OR RHEUMATOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. INITIAL CRITERIA CONTINUED: (7) CROHN'S DISEASE WITH: (I) FISTULIZING OR SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO (1) ONE OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPURINE, OR METHOTREXATE FOR 3 MONTHS, AND (2) ONE OF THE FOLLOWING: HUMIRA OR HADLIMA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

PART B PREREQUISITE

N/A

SABRIL

MEDICATION(S)
VIGABATRIN, VIGADRONE, VIGPODER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR COMPLEX PARTIAL SEIZURES: DOCUMENTED FAILURE ON TWO OTHER FORMULARY SEIZURE MEDICATIONS SUCH AS CARBAMAZEPINE, DIVALPROEX, LEVETIRACETAM, GABAPENTIN, TOPIRAMATE, AND OTHERS OR CONTRAINDICATIONS TO THEIR USE. FOR INFANTILE SPASMS - APPROVE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

SAVELLA

MEDICATION(S)
SAVELLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO GABAPENTIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SEROSTIM

MEDICATION(S)
SEROSTIM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT OTHER THERAPIES HAVE PROVEN INEFFECTIVE FOR HIV-INFECTED PATIENTS DIAGNOSED WITH SIGNIFICANT WASTING.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SIGNIFOR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL: DOCUMENTATION OF BENEFICIAL RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SILDENAFIL

MEDICATION(S)
SILDENAFIL 20 MG TABLET (GENERIC FOR REVATIO)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

PART B PREREQUISITE
N/A

SIMPONI

MEDICATION(S)
SIMPONI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE SIMPONI CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, RINVOQ AND COSENTYX, OR (2) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, STELARA, TREMFYA, RINVOQ, SKYRIZI AND COSENTYX, OR (3) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (4) ULCERATIVE COLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE STELARA, RINVOQ, HADLIMA, AND HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR GASTROENTEROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

SIVEXTRO

MEDICATION(S)
SIVEXTRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE, TRANSPLANT, HEMATOLOGY OR ONCOLOGY SPECIALIST.

COVERAGE DURATION
6 DAYS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

SKYRIZI

MEDICATION(S)
SKYRIZI, SKYRIZI ON-BODY, SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE SKYRIZI CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (2) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) CROHN'S DISEASE WITH: (I) FISTULIZING OR SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO 1 OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPURINE, OR METHOTREXATE FOR 3 MONTHS. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR GASTROENTEROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

SOMATROPIN

MEDICATION(S)
NORDITROPIN FLEXPRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA FOR CHILDREN: EITHER 1 OR 2: (1) SHORT STATURE INITIAL: A) CURRENT HEIGHT IS 2.25 OR MORE STANDARD DEVIATIONS BELOW NORMAL, OR B) TARGET ADULT HEIGHT OF 2 OR MORE STANDARD DEVIATIONS BELOW MIDPARENTAL HEIGHT, OR C) HEIGHT VELOCITY OF MINUS 2 OR MORE STANDARD DEVIATIONS FOR AGE AND TANNER STAGE, AND D) GROWTH HORMONE (GH) PROVOCATIVE TESTING (GH PEAK LESS THAN 10 NG/ML), OR E) SERUM IGF LEVELS (IGF-1 OR IGFBP-3) LESS THAN 1 STANDARD DEVIATION BELOW NORMAL, OR F) IGF GENERATION TEST (STIMULATE LEVEL 3 TIMES BASELINE OR GREATER THAN 250MG/ML). (1) SHORT STATURE RENEWAL: A) DOCUMENTATION OF POSITIVE RESPONSE, AND B) GROWTH VELOCITY IS GREATER THAN OR EQUAL TO 2 CM/YEAR, AND C) DOCUMENTATION HAS BEEN PROVIDED THAT EPIPHYSES (GROWTH PLATES) REMAIN OPEN. (2) DIAGNOSIS OF PANHYPOPITUITARISM, PRADER-WILLI, TURNER SYNDROME, OR NOONAN SYNDROME AND EPIPHYSES ARE NOT CLOSED. CRITERIA FOR ADULTS: PATIENT HAS GROWTH HORMONE DEFICIENCY (GHD) WITH 1 OR 2 AND 3 AND 4 AND 5 LISTED BELOW: (1) HISTORY OF HYPOTHALAMIC OR PITUITARY DISEASE OR HISTORY OF CRANIAL IRRADIATION, OR (2) LOW IGF-1 LEVELS BASED ON AGE ADJUSTED VALUES AND SERUM GROWTH HORMONE CONCENTRATION OF LESS THAN 5 NG/ML (PEAK LEVELS) FOLLOWING STIMULATION TESTING. ITT (INSULIN TOLERANCE TEST) IS THE DIAGNOSTIC TEST OF CHOICE UNLESS CONTRAINDICATED, AND (3) COMPLETE PITUITARY HORMONE FUNCTION HAS BEEN TESTED AND REPLACED WHEN APPROPRIATE, AND (4) THREE OF THE FOLLOWING: A) ALTERED BODY COMPOSITION WITH INCREASED BODY FAT MASS AND DECREASED LEAN BODY MASS, OR B) DECREASED MUSCLE STRENGTH AND EXERCISE CAPACITY, OR C) REDUCED BONE DENSITY OR PRESENCE OF A FRAGILITY FRACTURE, OR

D) POOR SLEEP, OR E) IMPAIRED SENSE OF WELL BEING, AND (5) SECONDARY MEDICAL ILLNESSES THAT AFFECT GH HAVE BEEN RULED OUT.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.

COVERAGE DURATION

FOR SHORT STATURE: 6 MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET. ALL OTHERS: 12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

SPRAVATO

MEDICATION(S)
SPRAVATO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: (1) PRESCRIBED FOR PATIENTS WITH TREATMENT-RESISTANT DEPRESSION (FOR PATIENTS WITH AN INADEQUATE RESPONSE TO THREE OR MORE CLASSES OF THERAPIES), AND (2) A BASELINE MEASUREMENT OF DEPRESSION IS REQUIRED. DOCUMENTATION CAN INCLUDE PHQ9 SCORES OR SUICIDE RISK ASSESSMENT, AND (3) DOCUMENTATION OF COMPLIANCE WITH THE REMS CERTIFICATION PROGRAM RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY PROVIDER WITHIN THE PAST 12 MONTHS, AND, (2) PATIENT HAS BEEN ADHERENT TO THERAPY, AND, (3) DOCUMENTATION OF A POSITIVE RESPONSE IS REQUIRED.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A BEHAVIORAL HEALTH PROVIDER

COVERAGE DURATION
CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

STELARA

MEDICATION(S)
STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE STELARA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) CROHN'S DISEASE WITH: (I) FISTULIZING OR SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPURINE, OR METHOTREXATE FOR 3 MONTHS , OR (2) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (3) PSORIATIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR ONE MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (4) ULCERATIVE COLITIS WITH: (I) SEVERE DISEASE, OR (II) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: SULFASALAZINE, MESALAMINE, BALSALAZIDE, PREDNISONE, BUDESONIDE, AZATHIOPRINE, 6-MERCAPTOPURINE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR GASTROENTEROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

STIRIPENTOL

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

STRENSIQ

MEDICATION(S)
STRENSIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF (1) PERINATAL/INFANTILE- OR JUVENILE-ONSET HYPOPHOSPHATASIA (HPP), AND (2) DIAGNOSIS CONFIRMED BY (A) GENETIC TESTING POSITIVE FOR TISSUE-NONSPECIFIC ALKALINE PHOSPHATASE (TNSALP) GENE MUTATION, OR (B) TWO OF THE FOLLOWING: (I) LOW BASELINE ALKALINE PHOSPHATASE (ALP) ACTIVITY, AGE ADJUSTED, AND (II) ELEVATED ALP SUBSTRATE LEVELS (INCREASE SERUM PYRIDOXAL 5-PHOSPHATE (PLP) OR URINARY PHOSPHOETHANOLAMINE (PEA). RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION OF A POSITIVE RESPONSE.

AGE RESTRICTION
18 YEARS OR YOUNGER AT DISEASE ONSET

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY, OR SPECIALIST IN GENETICS OR METABOLISM

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

SUCRALFATE

MEDICATION(S)
SUCRALFATE 1 GM/10 ML SUSP, SUCRALFATE 1 GM/10 ML SUSP CUP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

SUNOSI

MEDICATION(S)
SUNOSI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF TRIAL AND FAILURE OR CONTRAINDICATION TO MODAFINIL OR ARMODAFINIL.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A SLEEP SPECIALIST OR A NEUROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TADALAFIL

MEDICATION(S)
TADALAFIL 20 MG TABLET (GENERIC FOR ADCIRCA)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION (PAH) AS CONFIRMED BY NEGATIVE RESPONSE TO ACUTE PULMONARY VASODILATOR TESTING OR A TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF CLINICAL EFFECTIVENESS INCLUDING BUT NOT LIMITED TO IMPROVED HEMODYNAMIC STATUS OR REDUCTION IN HOSPITALIZATIONS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

PART B PREREQUISITE
N/A

TALICIA

MEDICATION(S)
TALICIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
RESERVED FOR PATIENTS WHO HAVE MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE FIRST-LINE OPTION. FIRST LINE OPTIONS INCLUDE TRIPLE THERAPY (PROTON PUMP INHIBITOR, CLARITHROMYCIN, AND AMOXICILLIN OR METRONIDAZOLE) AND QUADRUPLE THERAPY (PROTON PUMP INHIBITOR, BISMUTH, TETRACYCLINE OR MINOCYCLINE, AND METRONIDAZOLE).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 DAYS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

THALASSEMIA AGENTS

MEDICATION(S)
DEFERASIROX, DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY), FERRIPROX 100 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY HEMATOLOGY AND ONCOLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

THIOLA

MEDICATION(S)
TIOPRONIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY UROLOGY OR NEPHROLOGY.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

TREMFYA

MEDICATION(S)
TREMFYA, TREMFYA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE TREMFYA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) PLAQUE PSORIASIS WITH AT LEAST 3% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 3 MONTHS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, OR ACITRETIN, OR (2) PSORIATIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR ONE MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

TRIENTINE

MEDICATION(S)
TRIENTINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF WILSON'S DISEASE AND (2) DEMONSTRATED INTOLERANCE OR MEDICAL CONTRAINDICATION TO PENICILLAMINE. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, AND HEPATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

TRIKAFTA

MEDICATION(S)
TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE TRIKAFTA CONCURRENTLY WITH OTHER CFTR MODULATOR THERAPIES (ANY CURRENT CFTR MODULATOR THERAPIES WILL BE DISCONTINUED PRIOR TO INITIATION OF TRIKAFTA).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CYSTIC FIBROSIS, AND (2) PATIENT HAS AT LEAST ONE F508DEL MUTATION ON THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE (HOMOZYGOUS OR HETEROZYGOUS MUTATION) OR A MUTATION IN THE CFTR GENE THAT IS RESPONSIVE BASED ON IN VITRO DATA. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PROVIDER IN THE PAST 12 MONTHS, AND (2) PROVIDER ATTESTS PATIENT CONTINOUS TO CLINICALLY BENEFIT FROM THERAPY (EXAMPLE, IMPROVED FEV1 OR REDUCTION IN PULMONARY EXACERBATIONS).

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 2 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY PULMONOLOGIST OR A SPECIALIST FROM A CYSTIC FIBROSIS TREATMENT CENTER.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

TYMLOS

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF: (A) FRAGILITY FRACTURE OF THE SPINE OR HIP WITHIN THE LAST FIVE YEARS, OR (B) SEVERE OSTEOPOROSIS WITH A T-SCORE OF SPINE, HIP OR FEMORAL NECK OF MINUS 3.5 OR LOWER, OR (C) OSTEOPOROSIS WITH A T-SCORE OF MINUS 2.5 OR LOWER AND (I) INTOLERANCE OR CONTRAINDICATION TO BISPHOSPHONATE THERAPY, OR (II) PROGRESSIVE BONE LOSS DEFINED AS BONE LOSS OF THREE PERCENT OR HIGHER DESPITE THERAPY WITH BISPHOSPHONATES.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
APPROVALS ARE LIMITED TO 2 YEARS.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VALCHLOR

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
APPROVALS ARE LIMITED TO A QUANTITY OF TWO 60 GRAM TUBES PER MONTH.

PART B PREREQUISITE
N/A

VASCEPA

MEDICATION(S)
ICOSAPENT ETHYL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENTS WITH CARDIOVASCULAR DISEASE OR WITH DIABETES AND OTHER RISK FACTORS WITH (A) CURRENTLY RECEIVING A HIGH INTENSITY STATIN (ATORVASTATIN 40-80 MG DAILY OR ROSUVASTATIN 20-40 MG DAILY) OR HAVING AN INTOLERANCE OR CONTRAINDICATION TO A STATIN, AND (B) A FASTING TRIGLYCERIDE LEVEL GREATER THAN 150 MG/DL, OR (2) FOR HYPERGLYCERIDEMIA (TRIGLYCERIDE LEVELS EQUAL TO OR HIGHER THAN 500 MG/DL) WITH AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO GEMFIBROZIL OR FENOFIBRATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

VERQUVO

MEDICATION(S)
VERQUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH AT LEAST TWO OF THE FOLLOWING THERAPIES: (A) ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS, ANGIOTENSIN II RECEPTOR BLOCKERS (ARB) OR ANGIOTENSIN RECEPTOR-NEPRILYSIN INHIBITORS (ARNI), (B) BETA-BLOCKERS, OR (C) ALDOSTERONE ANTAGONISTS (SPIRONOLACTONE OR EPLERENONE). RENEWAL CRITERIA: DOCUMENTATION OF (1) POSITIVE RESPONSE AND (2) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VORAXAPAR

MEDICATION(S)
ZONTIVITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO CLOPIDOGREL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VOSEVI

MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

COVERAGE DURATION
12 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES.

OTHER CRITERIA
DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF ONE TABLET DAILY.

PART B PREREQUISITE
N/A

VOWST

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
VOWST MAY NOT BE USED FOR TREATMENT OF CLOSTRIDIOIDES DIFFICILE INFECTION (CDI).

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF RECURRENT CLOSTRIDIOIDES DIFFICILE INFECTION (CDI). RECURRENT CDI IS DEFINED AS THREE OR MORE PREVIOUS EPISODES TREATED WITH ANTIBIOTICS SUCH AS VANCOMYCIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
10 DAYS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. LIMITED TO A SINGLE TREATMENT COURSE.

PART B PREREQUISITE
N/A

VYNDAMAX

MEDICATION(S)
VYNDAMAX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE VYNDAMAX CONCURRENTLY WITH ONPATTRO OR TEGSEDI.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT IS DIAGNOSED WITH WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS CARDIOMYOPATHY, AND (2) PATIENT HAS CLINICAL HISTORY OF HEART FAILURE (HF), WITH DOCUMENTATION OF EITHER OF THE FOLLOWING: (A) AT LEAST 1 PRIOR HOSPITALIZATION FOR HF, OR (B) CLINICAL EVIDENCE OF HF (WITHOUT HOSPITALIZATION) MANIFESTED BY SIGNS OR SYMPTOMS OF VOLUME OVERLOAD OR ELEVATED INTRA-CARDIAC PRESSURES (E.G., ELEVATED JUGULAR VENOUS PRESSURE, SHORTNESS OF BREATH OR SIGNS OF PULMONARY CONGESTION ON X-RAY OR AUSCULTATION, PERIPHERAL EDEMA) THAT REQUIRES TREATMENT WITH A DIURETIC FOR IMPROVEMENT, AND (3) PATIENT IS NEGATIVE FOR LIGHT CHAIN AMYLOIDOSIS. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THEIR PRESCRIBER IN THE PAST 12 MONTHS, AND (2) MEDICATION HAS DEMONSTRATED EFFICACY.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

VYNDAQEL

MEDICATION(S)
VYNDAQEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT IS DIAGNOSED WITH WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS CARDIOMYOPATHY, AND (2) PATIENT HAS CLINICAL HISTORY OF HEART FAILURE (HF), WITH DOCUMENTATION OF EITHER OF THE FOLLOWING: (A) AT LEAST 1 PRIOR HOSPITALIZATION FOR HF, OR (B) CLINICAL EVIDENCE OF HF (WITHOUT HOSPITALIZATION) MANIFESTED BY SIGNS OR SYMPTOMS OF VOLUME OVERLOAD OR ELEVATED INTRA-CARDIAC PRESSURES (E.G., ELEVATED JUGULAR VENOUS PRESSURE, SHORTNESS OF BREATH OR SIGNS OF PULMONARY CONGESTION ON X-RAY OR AUSCULTATION, PERIPHERAL EDEMA) THAT REQUIRES TREATMENT WITH A DIURETIC FOR IMPROVEMENT, AND (3) PATIENT IS NEGATIVE FOR LIGHT CHAIN AMYLOIDOSIS. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THEIR PRESCRIBER IN THE PAST 12 MONTHS, AND (2) MEDICATION HAS DEMONSTRATED EFFICACY.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

WAKIX

MEDICATION(S)
WAKIX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE WAKIX CONCURRENTLY WITH XYREM OR XYWAV.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF NARCOLEPSY WITH CATAPLEXY AND ONE MONTH TRIAL AND FAILURE OR A MEDICAL CONTRAINDICATION WITH AN ANTIDEPRESSANT USED IN THE TREATMENT OF CATAPLEXY (SUCH AS FLUOXETINE OR CLOMIPRAMINE) OR (2) DIAGNOSIS OF NARCOLEPSY WITHOUT CATAPLEXY AND THE PATIENT HAS CONTRAINDICATIONS OR HAD NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH TWO OF THE FOLLOWING THERAPIES: (A) MODAFINIL OR ARMODAFINIL OR (B) SUNOSI. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PROVIDER IN THE PAST 12 MONTHS, AND (2) MEDICAL CHART DOCUMENTATION OF EFFICACY, SUCH AS IMPROVEMENT IN EXCESSIVE DAYTIME SLEEPINESS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A PROVIDER EXPERIENCED IN THE MANAGEMENT OF NARCOLEPSY INCLUDING BUT NOT LIMITED TO, NEUROLOGIST AND SLEEP SPECIALIST.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

XATMEP

MEDICATION(S)
JYLAMVO, XATMEP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH METHOTREXATE TABLETS OR INJECTION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

PART B PREREQUISITE
N/A

XELJANZ

MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE XELJANZ CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) PSORIATIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, STELARA, TREMFYA, RINVOQ, SKYRIZI AND COSENTYX, OR (2) RHEUMATOID ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (3) ULCERATIVE COLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE STELARA, RINVOQ, HADLIMA, AND HUMIRA, OR (4) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HADLIMA, AND HUMIRA, OR (5) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, RINVOQ AND COSENTYX. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR GASTROENTEROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

XENAZINE

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY NEUROLOGY.

COVERAGE DURATION
THREE MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

XENLETA

MEDICATION(S)
XENLETA 600 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR DIAGNOSIS OF COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP), DOCUMENTATION THAT IT IS CAUSED BY A SUSCEPTIBLE BACTERIA, AND (3) DOCUMENTATION OF INADEQUATE RESPONSE OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS TO WHICH THE BACTERIA IS SUSCEPTIBLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY INFECTIOUS DISEASE SPECIALIST.

COVERAGE DURATION
5 DAYS

OTHER CRITERIA
DOSE IS LIMITED TO 600 MG EVERY 12 HOURS FOR 5 DAYS.

PART B PREREQUISITE
N/A

XERMELO

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF RENEWAL CRITERIA ARE MET.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XGEVA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) FOR PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH BONE METASTESES FROM SOLID TUMORS, OR (2) FOR TREATMENT OF ADULTS AND SKELATALLY MATURE ADOLESCENTS WITH GIANT CELL TUMOR OF BONE THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, OR (3) DIAGNOSIS OF HYPERCALCEMIA OF MALIGNANCY REFRACTORY TO BISPHOSPHONATE THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

XIFAXAN

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF HEPATIC ENCEPHALOPATHY AND DOCUMENTATION THAT SIDE EFFECTS HAVE LIMITED THE DOSE OF LACTULOSE, OR (2) DIAGNOSIS OF TRAVELER'S DIARRHEA AND DOCUMENTATION OF TRIAL AND FAILURE OF OR CONTRAINDICATIONS TO CIPROFLOXACIN, OR (3) DIAGNOSIS OF MODERATE TO SEVERE IRRITABLE BOWEL DISEASE, INCLUDING BLOATING, WITHOUT CONSTIPATION AND WITH (A) AN INADEQUATE RESPONSE TO FIRST LINE THERAPY INCLUDING AN ANTISPASMODIC AGENT SUCH AS DICYCLOMINE AND AN ANTIDIARRHEAL AGENT SUCH AS LOPERAMIDE OR DIPHENOXYLATE/ATROPINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY FOR TREATMENT OF IRRITABLE BOWEL DISEASE

COVERAGE DURATION
HEPATIC ENCEPHALOPATHY: 12 MONTHS, IBS-D: 14 DAYS, TRAVELERS' DIARRHEA: 3 DAYS

OTHER CRITERIA
IRRITABLE BOWEL DISEASE: DOSE IS LIMITED TO 550 MG THREE TIMES DAILY FOR 14 DAYS. RETREATMENT IS LIMITED TO PATIENTS WITH A POSITIVE RESPONSE AND LIMITED TO A MAXIMUM OF TWO, 14 DAY TREATMENTS. TRAVELER'S DIARRHEA: 3 DAYS.

PART B PREREQUISITE

N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE XOLAIR CONCURRENTLY WITH ANOTHER BIOLOGIC THERAPY FOR THE TREATMENT OF ASTHMA SUCH AS CINQAIR, DUPIXENT, FASENRA OR NUCALA.

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. FOR SEVERE ASTHMA: INITIAL CRITERIA: (1) FOR PATIENTS DIAGNOSED WITH ASTHMA THEY HAVE A POSITIVE SKIN PRICK OR BLOOD TEST TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL GREATER THAN OR EQUAL TO 30 IU/ML, AND (2) PATIENT HAS INADEQUATE ASTHMA CONTROL DESPITE USE OF AN INHALED STEROID (SUCH AS FLUTICASONE PROPIONATE HFA), AND AT LEAST ONE OTHER MAINTENANCE MEDICATION: (A) LEUKOTRIENE RECEPTOR ANTAGONIST, (B) LONG-ACTING BETA-AGONIST (SUCH AS SEREVENT), (C) LONG-ACTING MUSCARINIC ANTAGONIST (SUCH AS INCRUSE ELLIPTA), OR (D) THEOPHYLLINE, AND (3) INADEQUATE ASTHMA CONTROL DESPITE STANDARD THERAPIES IS DEFINED AS ONE OF THE FOLLOWING: (A) AT LEAST ONE EXACERBATION REQUIRING ORAL SYSTEMIC CORTICOSTEROIDS IN THE LAST 12 MONTHS, OR (B) AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT IN THE LAST 12 MONTHS. FOR CHRONIC URTICARIA: DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO A MAXIMALLY TOLERATED DOSE OF AN H1 ANTIHISTAMINE (SUCH AS LEVOCETIRIZINE). FOR CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: (1) PATIENT IS CURRENTLY RECEIVING THERAPY WITH AN INTRANASAL CORTICOSTEROID OR HAS TRIED AND FAILED OR HAS A MEDICAL CONTRAINDICATION TO INTRANASAL CORTICOSTEROIDS. RENEWAL CRITERIA: (1) FOR NASAL POLYPS, DOCUMENTATION OF POSITIVE RESPONSE. (2) FOR ASTHMA, (A) CONTINUED USE OF AN INHALED STEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, (B) PATIENT HAS A POSITIVE RESPONSE AS DEFINED BY ONE OF THE FOLLOWING: (I) DECREASED FREQUENCY OF EXACERBATIONS

(II) DECREASED USE OF RESCUE MEDICATIONS, (III) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (IV) IMPROVEMENT IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ASTHMA SPECIALIST, ALLERGIST, PULMONOLOGIST, IMMUNOLOGIST, OTOLARYNGOLOGIST OR DERMATOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

XYREM

MEDICATION(S)
SODIUM OXYBATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE SODIUM OXYBATE CONCURRENTLY WITH SEDATIVE HYPNOTICS, XYWAV OR WAKIX.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CATAPLEXY ASSOCIATED WITH NARCOLEPSY AND THE PATIENT HAS A MEDICAL CONTRAINDICATION OR NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH EACH OF THE FOLLOWING THERAPIES: (A) AN ANTIDEPRESSANT USED IN THE TREATMENT OF CATAPLEXY (SUCH AS FLUOXETINE OR CLOMIPRAMINE) AND (B) WAKIX (WAKIX IS NOT REQUIRED FOR PATIENTS LESS THAN 18 YEARS OF AGE), OR (2) DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY AND THE PATIENT HAS A MEDICAL CONTRAINDICATION OR NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH WAKIX AND SUNOSI (WAKIX AND SUNOSI ARE NOT REQUIRED FOR PATIENTS LESS THAN 18 YEARS OF AGE). RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PROVIDER IN THE PAST 12 MONTHS, AND (2) MEDICAL CHART DOCUMENTATION OF EFFICACY, SUCH AS REDUCTION IN SYMPTOMS OF DAYTIME SLEEPINESS OR REDUCTION IN FREQUENCY OF CATAPLEXY ATTACKS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 7 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A PROVIDER EXPERIENCED IN THE MANAGEMENT OF NARCOLEPSY INCLUDING BUT NOT LIMITED TO, NEUROLOGIST AND SLEEP SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

XYWAV

MEDICATION(S)
XYWAV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE XYWAV CONCURRENTLY WITH SEDATIVE HYPNOTICS, XYREM OR WAKIX.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CATAPLEXY ASSOCIATED WITH NARCOLEPSY AND THE PATIENT HAS A MEDICAL CONTRAINDICATION OR NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH EACH OF THE FOLLOWING THERAPIES: (A) AN ANTIDEPRESSANT USED IN THE TREATMENT OF CATAPLEXY (SUCH AS FLUOXETINE OR CLOMIPRAMINE) AND (B) WAKIX (WAKIX IS NOT REQUIRED FOR PATIENTS LESS THAN 18 YEARS OF AGE), OR (2) DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY AND THE PATIENT HAS A MEDICAL CONTRAINDICATION OR NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH WAKIX (WAKIX IS NOT REQUIRED FOR PATIENTS LESS THAN 18 YEARS OF AGE) AND SUNOSI, OR (3) DIAGNOSIS OF IDIOPATHIC HYPERSOMNIA. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PROVIDER IN THE PAST 12 MONTHS, AND (2) MEDICAL CHART DOCUMENTATION OF EFFICACY, SUCH AS REDUCTION IN SYMPTOMS OF DAYTIME SLEEPINESS OR REDUCTION IN FREQUENCY OF CATAPLEXY ATTACKS.

AGE RESTRICTION
RESERVED FOR PATIENTS AGE 7 AND OLDER.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY A PROVIDER EXPERIENCED IN THE MANAGEMENT OF NARCOLEPSY INCLUDING BUT NOT LIMITED TO, NEUROLOGIST AND SLEEP SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

ZEPOSIA

MEDICATION(S)
ZEPOSIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE ZEPOSIA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) ULCERATIVE COLITIS WITH DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE STELARA, RINVOQ, HADLIMA, AND HUMIRA, OR (2) RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS), INCLUDING CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS FOR MULTIPLE SCLEROSIS. EXAMPLES OF PREFERRED DRUGS INCLUDE: GILENYA, DIMETHYL FUMARATE, PLEGRIDY, AVONEX, ETC. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR GASTROENTEROLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

ZOKINVY

MEDICATION(S)
ZOKINVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF ADEQUATE LIVER AND RENAL FUNCTION. RENEWAL CRITERIA: (1) THE PROVIDER ATTESTS THAT THE PATIENT HAS HAD A RESPONSE TO THE MEDICATION AND (2) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS.

AGE RESTRICTION
RESERVED FOR PATIENTS 12 MONTHS AND OLDER WITH BODY SURFACE AREA OF AT LEAST 0.39 M2.

PRESCRIBER RESTRICTION
RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST OR GENETICIST.

COVERAGE DURATION
SIX MONTHS, THEN 12 MONTHS IF POSITIVE RESPONSE.

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE
N/A

ZYFLO

MEDICATION(S)
ZILEUTON ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF TRIAL AND FAILURE OR CONTRAINDICATION TO MONTELUKAST.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A