HealthPartners®

2025 Medicare Part D
Prior Authorization Requirements

Effective: September 1st, 2025

Formulary ID 25128, Version 18
Last Updated: 08/20/2025

ABIRATERONE

MEDICATION(S)
ABIRATERONE ACETATE, ABIRTEGA

PA INDICATION INDICATOR
3 - All Medically-Accepted 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) GENETIC TESTING HAS BEEN COMPLETED, IF REQUIRED, FOR THERAPY WITH THE REQUESTED AGENT AND RESULTS INDICATE THE REQUESTED AGENT IS APPROPRIATE, AND (3) PATIENT DOES NOT HAVE ANY FDA LABELED LIMITATIONS OF USE THAT IS NOT OTHERWISE SUPPORTED IN NCCN GUIDELINES, AND (4) ONE OF THE FOLLOWING: (A) THE REQUESTED AGENT IS FDA LABELED OR SUPPORTED BY COMPENDIA AS FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO THE FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (5) PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. FOR ABIRATERONE, (1) PATIENT HAS A DIAGNOSIS OF METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC) OR METASTATIC CASTRATION RESISTANT PROSTATE CANCER, AND (2) IF THE REQUEST IS FOR 500 MG TABLET, PLEASE PROVIDE A RATIONALE WHY PATIENT CANNOT USE THE 250 MG TABLET.

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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (A) TO REDUCE THE FREQUENCY AND SEVERITY OF SERIOUS INFECTIONS ASSOCIATED WITH CHRONIC GRANULOMATOUS DISEASE, OR (B) DELAYING THE TIME TO DISEASE PROGRESSION IN PATIENTS WITH SEVERE, MALIGNANT OSTEOPETROSIS.

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

ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: (A) MEAN PULMONARY ARTERY PRESSURE (PAP) EQUAL TO OR GREATER THAN 20 MMHG, (B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF EQUAL TO OR LOWER THAN 15 MMHG, AND (C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS, AND (3) FOR WHO GROUP 4 PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) BOTH OF THE FOLLOWING: (A) WHO FUNCTIONAL CLASS II-IV SYMPTOMS, AND (B) ONE OF THE FOLLOWING: NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

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 AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND PATIENT HAS GREATER THAN OR EQUAL TO 4 MIGRAINE DAYS PER MONTH. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
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

ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

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) PATIENT HAS ALPHA-1 ANTITRYPSIN DEFICIENCY (AATD) WITH CLINICALLY EVIDENT EMPHYSEMA, AND (A) PRETREATMENT SERUM ALPHA-1 ANTITRYPSIN (AAT) LEVEL LESS THAN 11 MICROMOLES/L (OR LESS THAN 80 MG/DL MEASURED BY RADIAL IMMUNODIFFUSION OR LESS THAN 57 MG/DL MEASURED BY NEPHELOMETRY), AND (B) PATIENT WILL CONTINUE CONVENTIONAL TREATMENT FOR EMPHYSEMA (SUCH AS BRONCHODILATORS). RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO 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

AMBRISENTAN

MEDICATION(S)
AMBRISENTAN

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 GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: (A) MEAN PULMONARY ARTERY PRESSURE (PAP) EQUAL TO OR GREATER THAN 20 MMHG, (B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF EQUAL TO OR LOWER THAN 15 MMHG, AND (C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS, AND (3) PATIENT DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

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
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) TESTOSTERONE DEFICIENCY OF LESS THAN 300 NG/DL. FOR TESTOSTERONE ENANTHATE, FOR DELAYED PUBERTY OR METASTATIC BREAST CANCER, APPROVE.

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)
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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO ANTI-SEIZURE MEDICATIONS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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

ANTIDEPRESSANTS - NON-PREFERRED AGENTS

MEDICATION(S)
AUVELITY, DRIZALMA SPRINKLE, FETZIMA, TRINTELLIX

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) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO PREFERRED ALTERNATIVE ANTIDEPRESSANTS, SUCH AS: CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, VENLAFAXINE, OR DULOXETINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

APOMORPHINE

MEDICATION(S)
APOMORPHINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH A 5-HT3 ANTAGONIST (SUCH AS ONDANSETRON, GRANISETRON).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR ACUTE, INTERMITTENT HYPOMOBILITY, "OFF" EPISODES ("END OF DOSE WEARING OFF" AND UNPREDICTABLE "ON/OFF" EPISODES) ASSOCIATED WITH ADVANCED PARKINSON'S DISEASE, AND (A) USED IN COMBINATION WITH AGENTS USED FOR THERAPY IN PARKINSON'S DISEASE (SUCH AS LEVODOPA, DOPAMINE AGONIST, MONOAMINE OXIDASE B INHIBITOR), AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO INBRIJA OR CARBIDOPA/LEVODOPA. RENEWAL CRITERIA: POSITIVE RESPONSE TO TREATMENT BASED ON OFF PERIOD SYMPTOMS.

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

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

APTIOM

MEDICATION(S)
ESLICARBAZEPINE ACETATE

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) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO ANTI-SEIZURE MEDICATIONS SUCH AS LAMOTRIGINE, LEVETIRACETAM, OR TOPIRAMATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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

ARANESP

MEDICATION(S)
ARANESP

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 CHRONIC KIDNEY DISEASE (CKD) OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL OF LESS THAN 10G/DL. RENEWAL CRITERIA: (1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS, OR (2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS, OR (3) CANCER CHEMOTHERAPY: (A) HEMOGLOBIN LEVEL OF LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.

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

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER BIOLOGIC AGENT.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS), INCLUDING FAMILIAL COLD AUTO INFLAMMATORY SYNDROME (FCAS) AND MUCKLE-WELLS SYNDROME (MWS), OR (2) DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) WITH GENETIC TESTING CONFIRMING MUTATION IN THE IL1RN GENE, OR (3) DIAGNOSIS OF RECURRENT PERICARDITIS DEFINED AS THREE OR MORE EPISODES OF SYMPTOMATIC PERICARDITIS IN THE PAST YEAR, AND (A) PATIENT HAS AN INFLAMMATORY PHENOTYPE CHARACTERIZED BY THE PRESENCE OF AT LEAST ONE INFLAMMATORY PROCESS WHEN PRESENTING WITH A RECURRENCE (SUCH AS FEVER, ELEVATED CRP, ELEVATED WBC COUNT, ETC), AND (B) 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 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
PRESCRIBED 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

ARMODAFINIL

MEDICATION(S)
ARMODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER TARGET AGENT SUCH AS MODAFINIL.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR OBSTRUCTIVE SLEEP APNEA (OSA), DIAGNOSIS OF OSA DEFINED BY ONE OF THE FOLLOWING: (A) 15 OR MORE OBSTRUCTIVE RESPIRATORY EVENTS PER HOUR OF SLEEP CONFIRMED BY A SLEEP STUDY, UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, OR (B) BOTH OF THE FOLLOWING: (I) FIVE OR MORE OBSTRUCTIVE RESPIRATORY EVENTS PER HOUR OF SLEEP CONFIRMED BY A SLEEP STUDY, UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, AND (II) AT LEAST ONE OF THE FOLLOWING SYMPTOMS: DAYTIME SLEEPINESS, UNINTENTIONAL SLEEP EPISODES DURING WAKEFULNESS, UNREFRESHING SLEEP, FATIGUE, INSOMNIA, WAKING UP BREATH HOLDING/GASPING/CHOKING, LOUD SNORING, OR BREATHING INTERRUPTIONS DURING SLEEP, OR (3) FOR SHIFT-WORK DISORDER (SWD), DIAGNOSIS OF SWD CONFIRMED BY (A) ONE OF THE FOLLOWING: (I) PATIENT IS WORKING AT LEAST FIVE OVERNIGHT SHIFTS PER MONTH, OR (II) SLEEP STUDY DEMONSTRATING LOSS OF A NORMAL SLEEP-WAKE PATTERN SUCH AS DISTURBED CHRONOBIOLOGIC RHYTHMICITY, AND (B) NO OTHER MEDICAL CONDITIONS OR MEDICATIONS ARE CAUSING THE SYMPTOMS OF EXCESSIVE SLEEPINESS OR INSOMNIA, OR (4) FOR NARCOLEPSY CONFIRMED WITH POLYSOMNOGRAPHY AND A MULTIPLE SLEEP LATENCY TEST (MSLT), UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, OR (5) ADJUNCTIVE THERAPY FOR TREATMENT-RESISTANT DEPRESSION DEFINED AS MAJOR DEPRESSIVE DISORDER (MDD) OR BIPOLAR DEPRESSION, AND AN INTOLERANCE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANTS FROM DIFFERENT CLASSES (SUCH AS AN SSRI, SNRI, BUPROPION). RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

ATTRUBY

MEDICATION(S)
ATTRUBY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

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

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT IS DIAGNOSED WITH WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS CARDIOMYOPATHY (ATTR-CM), AND (2) DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: (A) CARDIAC BIOPSY WITH POSITIVE CONGO RED STAINING AND ATTR CONFIRMATION BY MASS SPECTROMETRY OR IMMUNOFLUORESCENCE STAINING, OR (B) ALL OF THE FOLLOWING: (I) SERUM KAPPA/LAMBDA FREE LIGHT CHAIN RATIO 0.26 TO 1.65, AND (II) ABSENCE OF MONOCLONAL PROTEIN VIA SERUM PROTEIN IMMUNOFIXATION, AND (III) ABSENCE OF MONOCLONAL PROTEIN VIA URINE PROTEIN IMMUNOFIXATION, AND (IV) MYOCARDIAL UPTAKE OF 99MTC-PYP DEMONSTRATED BY A GREATER THAN 1.5 HEART-TO-CONTRALATERAL RATIO OR GRADE 2 OR GREATER VISUAL EVIDENCE, AND (3) PATIENT HAS DOCUMENTATION OF EITHER OF THE FOLLOWING: (A) AT LEAST ONE PRIOR CARDIOVASCULAR-RELATED HOSPITALIZATION, OR (B) CLINICAL SYMPTOMS OF CARDIOMYOPATHY (SUCH AS DYSPNEA, FATIGUE, ORTHOSTATIC HYPOTENSION, SYNCOPE, PERIPHERAL EDEMA), AND (4) 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
PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

ATYPICAL ANTIPSYCHOTIC AGENTS

MEDICATION(S)
CAPLYTA, COBENFY, COBENFY STARTER PACK, FANAPT, LYBALVI, MOLINDONE HCL, OPIPZA, 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) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO OF THE FOLLOWING ALTERNATIVES: LURASIDONE, 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: (1) TARDIVE DYSKINESIA WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO DISCONTINUATION OR DOSE MODIFICATION OF THE OFFENDING MEDICATION, OR (2) CHOREA ASSOCIATED WITH HUNTINGTON DISEASE.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
TARDIVE DYSKINESIA: 3 MOS, THEN 12 MOS IF POSITIVE RESPONSE, HUNTINGTON DISEASE: 12 MOS.

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

PART B PREREQUISITE
N/A

AVONEX

MEDICATION(S)
AVONEX, AVONEX (4 PACK), AVONEX PEN (4 PACK)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

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 MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER BIOLOGIC AGENT.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR ACTIVE, AUTOANTIBODY-POSITIVE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) WITHOUT SEVERE ACTIVE CENTRAL NERVOUS SYSTEM DISEASE, AND (A) DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: (I) ANTI-DOUBLE STRANDED DNA VALUE GREATER THAN 30 IU/ML, OR (II) LOW COMPLEMENT (C3/C4), OR (III) POSITIVE ANTI-SMITH ANTIBODIES, AND (B) PATIENT WILL CONTINUE STANDARD OF CARE TREATMENT FOR ACTIVE SLE [SUCH AS ANTIMALARIALS (E.G., HYDROXYCHLOROQUINE), CORTICOSTEROIDS (E.G., PREDNISONE), OR IMMUNOSUPPRESSANTS (E.G., METHOTREXATE, AZATHIOPRINE)] IN COMBINATION WITH THE REQUESTED AGENT, AND (C) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO OF THE FOLLOWING: (I) HYDROXYCHLOROQUINE, OR (II) IMMUNOSUPPRESSIVE AGENTS (SUCH AS MYCOPHENOLATE, AZATHIOPRINE, METHOTREXATE, ORAL CYCLOPHOSPHAMIDE), OR (III) ORAL CORTICOSTEROIDS (SUCH AS PREDNISONE, METHYLPREDNISOLONE), OR (3) FOR ACTIVE LUPUS NEPHRITIS (LN) WITHOUT SEVERE ACTIVE CENTRAL NERVOUS SYSTEM DISEASE, AND (A) PATIENT WILL CONTINUE STANDARD OF CARE TREATMENT FOR ACTIVE LN [SUCH AS CORTICOSTEROIDS (E.G., PREDNISONE, METHYLPREDNISOLONE), IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE, MYCOPHENOLATE) IN COMBINATION WITH THE REQUESTED AGENT, AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO MYCOPHENOLATE MOFETIL OR CYCLOPHOSPHAMIDE. RENEWAL CRITERIA: (1) POSITIVE RESPONSE TO THERAPY, AND (2) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

BETASERON

MEDICATION(S)
BETASERON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

BIVIGAM

MEDICATION(S)
BIVIGAM

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 PRIMARY IMMUNODEFICIENCY (SUCH AS CONGENITAL AGAMMAGLOBULINEMIA, COMMON VARIABLE IMMUNODEFICIENCY (CVID), SEVERE COMBINED IMMUNODEFICIENCY, WISKOTT-ALDRICH SYNDROME, X-LINKED AGAMMAGLOBULINEMIA (XLA), HUMORAL IMMUNODEFICIENCY, IGG SUBCLASS DEFICIENCY WITH OR WITHOUT IGA DEFICIENCY).

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

BOSENTAN

MEDICATION(S)
BOSENTAN 125 MG TABLET, BOSENTAN 62.5 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH CYCLOSPORINE A OR GLYBURIDE.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: (A) MEAN PULMONARY ARTERY PRESSURE (PAP) EQUAL TO OR GREATER THAN 20 MMHG, (B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF EQUAL TO OR LOWER THAN 15 MMHG, AND (C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS, AND (3) PATEINT DOES NOT HAVE ELEVATED LIVER ENZYMES (ALT, AST) MORE THAN 3 TIMES UPPER LIMIT OF NORMAL (ULN) OR INCREASE IN BILIRUBIN BY 2 OR MORE TIMES ULN.

AGE RESTRICTION
N/A

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

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) 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
PRESCRIBED 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

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: (1) THE PATIENT HAS BEEN SEEN WITHIN THE PAST 14 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

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

BRUKINSA

MEDICATION(S)
BRUKINSA 80 MG CAPSULE

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) PATIENT HAS A DIAGNOSIS OF MANTLE CELL LYMPHOMA (MCL), AND (A) INTOLERANCE OR MEDICAL CONTRAINDICATION TO CALQUENCE, OR (2) PATIENT HAS A DIAGNOSIS OF WALDENSTROM'S MACROGLOBULINEMIA (WM) AND (A) INTOLERANCE OR MEDICAL CONTRAINDICATION TO IMBRUVICA, OR (3) PATIENT HAS A DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL) AND (A) INTOLERANCE OR MEDICAL CONTRAINDICATION TO CALQUENCE OR IMBRUVICA, OR (4) PATIENT HAS A DIAGNOSIS OF RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL), OR (5) RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL). RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

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), AND (2) 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
ADULTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST/ONCOLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

CALQUENCE

MEDICATION(S)
CALQUENCE 100 MG 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
FOR NEW START PATIENTS: DIAGNOSIS OF: (1) CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL), OR (2) MANTLE CELL LYMPHOMA (MCL).

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

CARGLUMIC

MEDICATION(S)
CARGLUMIC ACID

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) ACUTE HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS), OR (2) CHRONIC HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS), OR (3) ACUTE HYPERAMMONEMIA DUE TO PROPIONIC ACIDEMIA (PA) OR METHYLMALONIC ACIDEMIA (MMA). RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS A REDUCTION IN THE NUMBER OF HYPERAMMONEMIC CRISES.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A PROVIDER SPECIALIZING IN GENETICS AND METABOLISM, OR NEPHROLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

CAYSTON

MEDICATION(S)
CAYSTON

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 USE IN CYSTIC FIBROSIS (CF) PATIENTS KNOWN TO HAVE PSEUDOMONAS AERUGINOSA IN THE LUNGS. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A SPECIALIST FROM A CYSTIC FIBROSIS TREATMENT CENTER, INFECTIOUS DISEASE SPECIALIST, OR A PULMONOLOGIST.

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 STAGE TWO OR THREE NEUROTROPHIC KERATITIS, AND (2) PROVIDER ATTESTATION THAT PATIENT HAS BEEN EDUCATED ON ADMINISTRATION TECHNIQUE, DRUG STORAGE, AND DRUG PREPARATION REQUIREMENTS, AND (3) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO PROPHYLACTIC ANTIBIOTICS.

AGE RESTRICTION
PATIENTS AGE 2 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST.

COVERAGE DURATION
EIGHT WEEKS

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

CERDELGA

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF TYPE I GAUCHER DISEASE RESULTING IN ONE OR MORE OF THE FOLLOWING: MODERATE TO SEVERE ANEMIA, THROMBOCYTOPENIA WITH BLEEDING TENDENCY, BONE DISEASE, SIGNIFICANT HEPATOMEGALY OR SPLENOMEGALY. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN IN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEMATOLOGY, HEPATOLOGY, OR NEPHROLOGY.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

CHOLBAM

MEDICATION(S)
CHOLBAM

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 A BILE ACID SYNTHESIS DISORDER (BAS) DUE TO SINGLE ENZYME DEFECTS, OR (2) DIAGNOSIS OF PEROXISOMAL DISORDERS (PDS) INCLUDING ZELLWEGER SPECTRUM DISORDERS WITH ALL OF THE FOLLOWING: (A) PATIENT EXHIBITS AT LEAST ONE OF THE FOLLOWING: (I) LIVER DISEASE (SUCH AS JAUNDICE, ELEVATED SERUM TRANSAMINASES), OR (II) STEATORRHEA, OR (III) COMPLICATIONS FROM DECREASED FAT-SOLUBLE VITAMIN ABSORPTION (SUCH AS POOR GROWTH), AND (B) WILL BE USED AS AN ADJUNCTIVE TREATMENT. RENEWAL CRITERIA: POSTIVE RESPONSE TO THERAPY SUCH AS IMPROVEMENT IN LIVER FUNCTION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, MEDICAL GENETICIST, GASTROENTEROLOGIST, OR OTHER SPECIALIST THAT TREATS INBORN ERRORS OF 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

CORLANOR

MEDICATION(S)
CORLANOR 5 MG/5 ML ORAL SOLN, IVABRADINE HCL

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) PATIENT HAS CHRONIC HEART FAILURE (CHF) WITH A LEFT VENTRICULAR EJECTION FRACTION LESS THAN OR EQUAL TO 35 PERCENT, AND (A) PATIENT HAS NEW YORK HEART ASSOCIATION (NYHA) CLASS II, III, OR IV SYMPTOMS, AND (B) PATIENT IS IN SINUS RHYTHM WITH A RESTING HEART RATE GREATER THAN OR EQUAL TO 70 BEATS PER MINUTE, AND (C) PATIENT HAS BEEN HOSPITALIZED FOR WORSENING HEART FAILURE (HF) WITHIN THE LAST 12 MONTHS, AND (D) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING THERAPIES: (I) ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITOR (SUCH AS LISINOPRIL), ANGIOTENSIN II RECEPTOR BLOCKER (ARB) (SUCH AS LOSARTAN), OR ANGIOTENSIN RECEPTOR-NEPRILYSIN INHIBITOR (ARNI) (SUCH AS ENTRESTO), OR (II) BETA-BLOCKER (SUCH AS BISOPROLOL), OR (III) ALDOSTERONE ANTAGONIST (SUCH AS SPIRONOLACTONE OR EPLERENONE), OR (IV) SGLT-2 INHIBITOR (SUCH AS JARDIANCE, SYNJARDY). RENEWAL CRITERIA: (1) POSITIVE RESPONSE TO THERAPY, 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

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) ACTIVE PSORIATIC ARTHRITIS, OR (2) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), 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 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, OR (7) HIDRADENITIS SUPPURATIVA. RENEWAL CRITERIA: 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: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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: POSITIVE CLINICAL TREATMENT EFFECT (SLIT LAMP EXAM RESULTS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, OR 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, AND (2) THE PATIENT IS CURRENTLY ABLE TO WALK 25 FEET, AND (3) PHYSICIAN ATTESTATION THAT PATIENT HAS DIFFICULTY WALKING, AND (4) PATIENT WILL (A) USE THE REQUESTED AGENT IN COMBINATION WITH A DISEASE MODIFYING AGENT (SUCH AS FINGOLIMOD, DIMETHYL FUMARATE, PLEGRIDY, AVONEX, ETC.), OR (B) HAS AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A DISEASE MODIFYING AGENT (SUCH AS FINGOLIMOD, DIMETHYL FUMARATE, PLEGRIDY, AVONEX, ETC.). RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

DEFERASIROX

MEDICATION(S)
DEFERASIROX

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 CHRONIC IRON OVERLOAD DUE TO A NON-TRANSFUSION DEPENDENT THALASSEMIA SYNDROME AND BOTH OF THE FOLLOWING: (A) A LIVER IRON (FE) CONCENTRATION (LIC) OF AT LEAST 5 MG FE PER GRAM OF DRY WEIGHT, AND (B) A SERUM FERRITIN GREATER THAN 300 MCG/L, OR (2) PATIENT HAS A DIAGNOSIS OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS, AND (A) PATIENT IS RECEIVING BLOOD TRANSFUSIONS AT REGULAR INTERVALS FOR VARIOUS CONDITIONS (SUCH AS THALASSEMIA SYNDROMES, MYELODYSPLASTIC SYNDROME, CHRONIC ANEMIA, SICKLE CELL DISEASE), AND (B) A SERUM FERRITIN GREATER THAN 1,000 MCG/L PRIOR TO STARTING THERAPY. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE

N/A

DEFERIPRONE

MEDICATION(S)
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
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D AND, (2) FOR THE DIAGNOSIS OF TRANSFUSION INDUCED IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES, SICKLE CELL DISEASE, OR OTHER ANEMIAS, (A) ABSOLUTE NEUTROPHIL COUNT (ANC) GREATER THAN 1.5 X 10E9/L, AND (B) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO PRIOR IRON CHELATION THERAPY SUCH AS DEFERASIROX, AND (C) FOR FERRIPROX SOLUTION, PATIENT HAS DIFFICULTY SWALLOWING. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS REDUCTION IN SERUM FERRITIN LEVELS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.

COVERAGE DURATION
12 MONTHS

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) 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
MAY NOT USE CONCURRENTLY WITH ANOTHER ACUTE MIGRAINE AGENT (SUCH AS TRIPTAN, 5HT-1F, ACUTE CGRP).

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) USED FOR ACUTE MIGRAINE HEADACHES WITH OR WITHOUT AURA, AND (3) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH TWO TRIPTAN MEDICATIONS SUCH AS SUMATRIPTAN, NARATRIPTAN OR RIZATRIPTAN. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PAIN SPECIALIST, OR HEADACHE SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DRONABINOL

MEDICATION(S)
DRONABINOL

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 NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY (CINV), AND (A) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A 5HT-3 RECEPTOR ANTAGONIST (SUCH AS ONDANSETRON), AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO PROCHLORPERAZINE, AND (C) PATIENT IS RECEIVING CANCER CHEMOTHERAPY, OR (3) FOR ANOREXIA WITH WEIGHT LOSS IN PATIENTS WITH AIDS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
AIDS ANOREXIA: THREE MONTHS, CINV: 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

DUPIXENT

MEDICATION(S)
DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML 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: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. FOR ATOPIC DERMATITIS: (1) MODERATE TO SEVERE ATOPIC DERMATITIS WITH AT LEAST 10% BODY SURFACE AREA (BSA) OR INVOLVEMENT WITH THE FACE, NECK, HANDS, FEET, GENITALS, OR INTERTRIGINOUS AREAS, AND (2) INTRACTABLE PRURITUS OR CRACKING/OOZING/BLEEDING OF AFFECTED SKIN, AND (3) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID OR ONE TOPICAL CALCINEURIN INHIBITOR SUCH AS TACROLIMUS OR PIMECROLIMUS. FOR ASTHMA: (1) 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 MEDIUM, HIGH-DOSE OR MAXIMALLY-TOLERATED DOSE 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, OR (C) 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 LASTING 3 OR MORE DAYS WITHIN 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) EOE CONFIRMED BY ESOPHAGOGASTRODUODENOSCOPY (EGD) WITH BIOPSY, AND (II) 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: (1) CHRONIC PRURITIS (ITCH MORE THAN 6 WEEKS), MULTIPLE PRURIGINOUS LESIONS, AND HISTORY OR SIGN OF A PROLONGED SCRATCHING BEHAVIOR, (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TOPICAL CORTICOSTEROID THERAPY, OR TOPICAL CALCIPOTRIOL. FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE: (1) EOSINOPHILIC PHENOTYPE, AND (2) USED IN COMBINATION WITH (I) A LONG-ACTING MUSCURANIC ANTAGONIST, AND (II) A LONG-ACTING BETA-2-AGONIST, AND (III) AN INHALED STEROID (E.G. TRELEGY ELLIPTA, BREZTRI AEROSPERE). RENEWAL CRITERIA: (1) FOR NASAL POLYPS, POSITIVE RESPONSE TO THERAPY. (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, POSITIVE RESPONSE TO THERAPY. (4) FOR PRURIGO NODULARIS, POSITIVE RESPONSE TO THERAPY. (5) FOR ATOPIC DERMATITIS, 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 AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND PATIENT HAS GREATER THAN OR EQUAL TO 4 MIGRAINE DAYS PER MONTH, OR (2) THE PATIENT HAS A DIAGNOSIS OF EPISODIC CLUSTER HEADACHES. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS MAJOR DEPRESSIVE DISORDER, AND (3) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO ANTIDEPRESSANTS, EACH FROM DIFFERENT ANTIDEPRESSANT SUB-CLASSES: (A) SSRI'S SUCH AS CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, AND (B) SNRI'S SUCH AS VENLAFAXINE OR DULOXETINE, AND (C) OTHER ANTIDEPRESSANTS SUCH AS MIRTAZAPINE OR BUPROPION.

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) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), 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) ACTIVE PSORIATIC ARTHRITIS. RENEWAL CRITERIA: 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: PATIENT HAS POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
PATIENTS AGE 5 AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST/ONCOLOGIST.

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 AND MAY NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

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

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

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

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

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

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) PRESCRIBED FOR PATIENTS WITH A DIAGNOSIS OF SEIZURES ASSOCIATED WITH ONE OF THE FOLLOWING: (A) LENNOX-GASTAUT SYNDROME OR, (B) DRAVET SYNDROME OR, (C) TUBEROUS SCLEROSIS COMPLEX AND, (2) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO ANTI-SEIZURE MEDICATIONS SUCH AS LAMOTRIGINE, TOPIRAMATE, CLOBAZAM, OR RUFINAMIDE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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

ERLEADA

MEDICATION(S)
ERLEADA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC, METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: NMCRPC, MCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG.

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

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) DIAGNOSIS OF MILD TO MODERATE ATOPIC DERMATITIS, AND (3) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO OF THE FOLLOWING: (A) A PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID, (B) PIMECROLIMUS CREAM, OR (C) TACROLIMUS OINTMENT (PIMECROLIMUS AND TACROLIMUS OINTMENT ARE NOT REQUIRED FOR PATIENTS LESS THAN 2 YEARS OF AGE).

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 60 MG/80 ML(0.75MG/ML)

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) 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: 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
PATIENTS AGE 2 MONTHS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A 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, ARIKAYCE, CASPOFUNGIN ACETATE, COLISTIMETHATE, CYCLOSERINE, DOJOLVI, ERAXIS, IMPAVIDO, INVEGA HAFYERA, JUBBONTI, LUPRON DEPOT-PED, METYROSINE, NAYZILAM, NUPLAZID, PENTAMIDINE 300 MG INJECT VIAL, PERSERIS, PLERIXAFOR, PRETOMANID, PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET, QUININE SULFATE, REZUROCK, SYNAREL, TOBI PODHALER, TOBRAMYCIN SULFATE, VALTOCO, VISTOGARD, ZYPREXA RELPREVV

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: POSITIVE RESPONSE TO 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

FDA-APPROVED INDICATIONS WITH BVD

MEDICATION(S)
ABELCET, AMPHOTERICIN B, AMPHOTERICIN B LIPOSOME

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. RENEWAL CRITERIA: POSITIVE RESPONSE TO 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. 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), 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, POSITIVE RESPONSE TO THERAPY.

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)
BONSITY, TERIPARATIDE

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) 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

FYCOMPA

MEDICATION(S)
FYCOMPA, PERAMPANEL

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 PARTIAL-ONSET SEIZURES: MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO BOTH TOPIRAMATE AND LACOSAMIDE, AND (3) FOR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES: MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO ANTI-SEIZURE MEDICATIONS SUCH AS LAMOTRIGINE, LEVETIRACETAM, OR TOPIRAMATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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

GAMASTAN

MEDICATION(S)
GAMASTAN

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 HEPATITIS A PROPHYLAXIS IN PATIENTS WITH EXPOSURE WITHIN THE PAST TWO WEEKS, OR (3) MEASLES (RUBEOLA) PROPHYLAXIS FOR PATIENTS WHO HAVE (A) BEEN EXPOSED TO MEASLES (RUBEOLA) WITHIN THE PAST SIX DAYS, AND (B) SUSCEPTIBLE TO INFECTION DEFINED AS ONE WHO HAS NOT BEEN VACCINATED AND HAS NOT HAD MEASLES PREVIOUSLY, OR (4) FOR PASSIVE IMMUNIZATION AGAINST VARICELLA IN IMMUNOSUPPRESSED PATIENTS WHERE VARICELLA-ZOSTER IMMUNE GLOBULIN IS UNAVAILABLE, OR (5) FOR RUBELLA PROPHYLAXIS IN EXPOSED PREGNANT PATIENTS WHO ARE SUSCEPTIBLE TO INFECTION DEFINED AS ONE WHO HAS NOT BEEN VACCINATED AND HAS NOT HAD RUBELLA PREVIOUSLY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

GAMMAGARD LIQUID

MEDICATION(S)
GAMMAGARD LIQUID

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 PRIMARY IMMUNODEFICIENCY (SUCH AS CONGENITAL AGAMMAGLOBULINEMIA, COMMON VARIABLE IMMUNODEFICIENCY (CVID), SEVERE COMBINED IMMUNODEFICIENCY, WISKOTT-ALDRICH SYNDROME, X-LINKED AGAMMAGLOBULINEMIA (XLA), HUMORAL IMMUNODEFICIENCY, IGG SUBCLASS DEFICIENCY WITH OR WITHOUT IGA DEFICIENCY), OR (3) USED AS MAINTENANCE THERAPY FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) TO PREVENT RELAPSE OF NEUROMUSCULAR DISABILITY AND IMPAIRMENT, AND DIAGNOSIS CONFIRMED BY PROGRESSIVE SYMPTOMS PRESENT FOR AT LEAST TWO MONTHS, OR (4) FOR MULTIFOCAL MOTOR NEUROPATHY (MMN) CONFIRMED BY (A) WEAKNESS WITH SLOWLY PROGRESSIVE OR STEPWISE PROGRESSIVE COURSE OVER AT LEAST ONE MONTH, AND (B) ASYMMETRIC INVOLVEMENT OF TWO OR MORE NERVES, AND (C) ABSENSE OF MOTOR NEURON SIGNS AND BULBAR SIGNS.

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

GAMUNEX-C/GAMMAKED

MEDICATION(S)
GAMMAKED, GAMUNEX-C

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 PRIMARY IMMUNODEFICIENCY (SUCH AS CONGENITAL AGAMMAGLOBULINEMIA, COMMON VARIABLE IMMUNODEFICIENCY (CVID), SEVERE COMBINED IMMUNODEFICIENCY, WISKOTT-ALDRICH SYNDROME, X-LINKED AGAMMAGLOBULINEMIA (XLA), HUMORAL IMMUNODEFICIENCY, IGG SUBCLASS DEFICIENCY WITH OR WITHOUT IGA DEFICIENCY), OR (3) USED AS MAINTENANCE THERAPY FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) TO PREVENT RELAPSE OF NEUROMUSCULAR DISABILITY AND IMPAIRMENT, AND DIAGNOSIS CONFIRMED BY PROGRESSIVE SYMPTOMS PRESENT FOR AT LEAST TWO MONTHS, OR (4) FOR TREATMENT OF IDIOPATHIC THROMBOCYTOPENIA PURPURA (ITP), AN INTOLERANCE OR MEDICAL CONTRAINDICATION TO ONE CONVENTIONAL THERAPY [SUCH AS CORTICOSTEROIDS (E.G., METHYLPREDNISOLONE) OR IMMUNOSUPPRESSANTS (E.G., AZATHIOPRINE)].

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

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 NUTRITION SUPPORT FOR AT LEAST ONE YEAR, AND (3) IN WHOM A TAPER FROM PARENTERAL REQUIREMENTS HAS NOT BEEN POSSIBLE OR PLANNED, AND (4) EITHER OF THE FOLLOWING: (A) FOR ADULT PATIENTS, HAVE HAD A COLONOSCOPY WITHIN THE PAST SIX MONTHS WITH REMOVAL OF ANY POLYPS, OR (B) PEDIATRIC PATIENTS LESS THAN 18 YEARS OF AGE HAVE HAD A FECAL OCCULT BLOOD TEST WITHIN THE PAST SIX MONTHS AND ONE OF THE FOLLOWING (I) NO UNEXPLAINED BLOOD IN STOOL, OR (II) UNEXPLAINED BLOOD IN THE STOOL AND A COLONOSCOPY OR SIGMOIDOSCOPY WAS PERFORMED. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.

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
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 THE RELIEF OF SYMPTOMS IN ADULTS WITH ACUTE AND RECURRENT DIABETIC GASTROPARESIS, AND (3) INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO PREFERRED MEDICATIONS: (1) METOCLOPRAMIDE SOLUTION AND (2) METOCLOPRAMIDE TABLETS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GLP-1 AGENTS

MEDICATION(S)
LIRAGLUTIDE, MOUNJARO, OZEMPIC, OZEMPIC .25 OR 0.5 PEN INJCTR (DOSE 3 ML), RYBELSUS, TRULICITY

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

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) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), 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 DISEASE, OR (II) 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) MODERATE TO SEVERE ULCERATIVE COLITIS, OR (7) HIDRADENITIS SUPPURATIVA, OR (8) NON-INFECTIOUS INTERMEDIATE, POSTERIOR AND PANUVEITIS, OR (9) ACTIVE PSORIATIC ARTHRITIS. RENEWAL CRITERIA: 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

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, 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

HIZENTRA

MEDICATION(S)
HIZENTRA

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 PRIMARY IMMUNODEFICIENCY (SUCH AS CONGENITAL AGAMMAGLOBULINEMIA, COMMON VARIABLE IMMUNODEFICIENCY (CVID), SEVERE COMBINED IMMUNODEFICIENCY, WISKOTT-ALDRICH SYNDROME, X-LINKED AGAMMAGLOBULINEMIA (XLA), HUMORAL IMMUNODEFICIENCY, IGG SUBCLASS DEFICIENCY WITH OR WITHOUT IGA DEFICIENCY), OR (3) USED AS MAINTENANCE THERAPY FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) TO PREVENT RELAPSE OF NEUROMUSCULAR DISABILITY AND IMPAIRMENT, AND DIAGNOSIS CONFIRMED BY PROGRESSIVE SYMPTOMS PRESENT FOR AT LEAST TWO MONTHS.

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

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS

MEDICATION(S)
JUXTAPID

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) 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: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST, OR LIPIDOLOGY 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

HUMIRA

MEDICATION(S)
HUMIRA, HUMIRA PEN, 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) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING FOR 3 MONTHS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (2) JUVENILE IDIOPATHIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING FOR 1 MONTH: TREATMENT WITH ONE NSAID OR METHOTREXATE, OR (3) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), 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 DISEASE, OR (II) 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) MODERATE TO SEVERE ULCERATIVE COLITIS, OR (7) HIDRADENITIS SUPPURATIVA, OR (8) NON-INFECTIOUS INTERMEDIATE, POSTERIOR AND PANUVEITIS, OR (9) ACTIVE

PSORIATIC ARTHRITIS. RENEWAL CRITERIA: 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

IBRANCE

MEDICATION(S)
IBRANCE

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: POSITIVE RESPONSE TO THERAPY.

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

ICATIBANT

MEDICATION(S)
ICATIBANT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER HAE AGENT INDICATED FOR TREATMENT OF ACUTE HAE ATTACKS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA (HAE), DIAGNOSIS CONFIRMED BY TWO CONFIRMATORY TESTS OF C1-INH ANTIGENIC LEVEL, C1-INH FUNCTIONAL LEVEL, AND C4 LEVEL AS FOLLOWS: (A) TYPE I DEFINED AS DECREASED QUANTITIES OF C4 AND C1 INHIBITOR (C1INH), OR (B) TYPE II DEFINED AS DECREASED QUANTITIES OF FUNCTIONAL C1INH, OR (C) A KNOWN-HAE CAUSING C1INH MUTATION SUCH AS A FACTOR XII MUTATION, ANGIOPOIETIN-1 (ANGPT1) MUTATION, PLASMINOGEN (PLG) MUTATION, KININOGEN1 MUTATION, HEPARAN SULFATE 3-O-SULFOTRANSFERASE 6 GENE MUTATION, OR MYOFERLIN GENE MUTATION, AND (3) MEDICATIONS KNOWN TO CAUSE ANGIOEDEMA (SUCH AS ESTROGENS, ACE INHIBITORS, ANGIOTENSIN II BLOCKERS) HAVE BEEN EVALUATED AND DISCONTINUED WHEN APPROPRIATE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS A DECREASE IN THE FREQUENCY OR SEVERITY OF ACUTE ATTACKS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

IMBRUVICA

MEDICATION(S)
IMBRUVICA 140 MG CAPSULE, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION

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
FOR NEW START PATIENTS: DIAGNOSIS OF: (1) CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL) WITH OR WITHOUT 17P DELETION, OR (2) WALDENSTROM'S MACROGLOBULINEMIA, OR (3) CHRONIC GRAFT VERSUS HOST DISEASE AFTER FAILURE OF AT LEAST ONE SYSTEMIC THERAPY (E.G. CORTICOSTEROIDS LIKE PREDNISONE OR METHYLPREDNISOLONE).

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

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: 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: POSITIVE RESPONSE TO TREATMENT BASED ON OFF PERIOD SYMPTOMS.

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

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

INQOVI

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted 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) GENETIC TESTING HAS BEEN COMPLETED, IF REQUIRED, FOR THERAPY WITH THE REQUESTED AGENT AND RESULTS INDICATE THE REQUESTED AGENT IS APPROPRIATE, AND (3) PATIENT DOES NOT HAVE ANY FDA LABELED LIMITATIONS OF USE THAT IS NOT OTHERWISE SUPPORTED IN NCCN GUIDELINES, AND (4) ONE OF THE FOLLOWING: (A) THE REQUESTED AGENT IS FDA LABELED OR SUPPORTED BY COMPENDIA AS FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO THE FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (5) PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. FOR INQOVI, (1) PATIENT HAS MYELODYSPLASTIC SYNDROMES (MDS), AND (2) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A NUCLEOSIDE METABOLIC INHIBITOR (AZACITIDINE) (PART B BEFORE PART D STEP THERAPY - APPLIES ONLY TO BENEFICIARIES ENROLLED IN AN MA-PD PLAN).

PART B PREREQUISITE

YES

INSULIN SUPPLIES

MEDICATION(S)
ALCOHOL PREP PADS, ALCOHOL SWABS, DROPSAFE PREP PADS, GNP STERILE GAUZE PADS 2" X 2", STERILE GAUZE PADS 2" X 2", GAUZE PADS & DRESSINGS , INSULIN PEN NEEDLE, INSULIN SYRINGE (DISP) U-100 0.3 ML, INSULIN SYRINGE (DISP) U-100 1 ML, INSULIN SYRINGE (DISP) U-100 1/2 ML, ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, FT STERILE PADS 2" X 2", TRUE COMFORT PRO ALCOHOL PADS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
ONLY COVERED UNDER PART D WHEN USED CONCURRENTLY WITH INSULIN

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

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
MAY NOT USE CONCURRENTLY WITH GLUCOCORTICOID REPLACEMENT THERAPY.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENTS WITH CUSHING'S 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 TWO OF THE FOLLOWING: KETOCONAZOLE AND PASIREOTIDE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY (REDUCTION IN 24-HOUR URINARY FREE CORTISOL FROM BASELINE).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.

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

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
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 OROPHARYNGEAL AND ESOPHAGEAL CANDIDIASIS.

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

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. MAY NOT USE CONCURRENTLY WITH ANOTHER CFTR MODULATOR AGENT FOR THE REQUESTED INDICATION.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CYSTIC FIBROSIS, AND (2) PATIENT HAS AT LEAST ONE MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE THAT IS RESPONSIVE TO THE PRESCRIBED DRUG BASED ON IN VITRO ASSAY DATA, AND (2) PATIENT IS NOT HOMOZYGOUS FOR THE F508DEL MUTATION. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH 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
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) URINE ALBUMIN-TO-CREATININE RATIO (UACR) GREATER THAN OR EQUAL TO 30 MG/G, AND (3) ESTIMATED GLOMERULAR FILTRATION RATE (EGFR) GREATER THAN OR EQUAL TO 25 ML/MIN/1.73M2, AND (4) SERUM POTASSIUM LEVEL LESS THAN OR EQUAL TO 5.0 MEQ/L BEFORE STARTING TREATMENT, AND (5) TRIAL OF AND WILL CONTINUE, MEDICAL CONTRAINDICATIONS, OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: (A) AN ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITOR (SUCH AS LISINOPRIL), OR (B) AN ANGIOTENSIN II RECEPTOR BLOCKER (ARB) (SUCH AS LOSARTAN), AND (6) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITOR (FOR EXAMPLE, JARDIANCE, SYNJARDY, ETC). RENEWAL CRITERIA: (1) POSITIVE RESPONSE TO THERAPY, AND (2) PATIENT CONTINUES TO BE ON, HAS A MEDICAL CONTRAINDICATION, OR INTOLERANCE TO AN ACE INHIBITOR AND AN ARB.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

KESIMPTA

MEDICATION(S)
KESIMPTA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

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 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: 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, KISQALI FEMARA CO-PACK

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) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST ONE PREFERRED DRUG. PREFERRED DRUGS INCLUDE: VERZENIO OR IBRANCE. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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
3 - All Medically-Accepted 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 PAIN ASSOCIATED WITH POSTHERPETIC NEURALGIA (PHN) OR PAIN ASSOCIATED WITH DIABETIC NEUROPATHY OR NEUROPATHIC PAIN ASSOCIATED WITH CANCER, OR CANCER TREATMENT, MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE CONVENTIONAL THERAPY [FOR EXAMPLE, GABAPENTIN, PREGABALIN] FOR THE REQUESTED INDICATION.

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

LINEZOLID

MEDICATION(S)
LINEZOLID, LINEZOLID-0.9% NACL, LINEZOLID-D5W

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY SIVEXTRO (TEDIZOLID) FOR THE SAME INFECTION

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND ONE OF THE FOLLOWING: (A) PATIENT HAS VANCOMYCIN-RESISTANT ENTEROCOCCUS FAECIUM, OR (B) PATIENT HAS PNEUMONIA CAUSED BY A SUSCEPTIBLE BACTERIA, AND ONE OF THE FOLLOWING: (I) AN INADEQUATE RESPONSE, MEDICAL CONTRAINDICATION, OR RESISTANCE TO TWO OF THE FOLLOWING: BETA-LACTAMS, MACROLIDES, CLINDAMYCIN, TETRACYCLINES, OR CO-TRIMOXAZOLE, OR (II) AN INADEQUATE RESPONSE, MEDICAL CONTRAINDICATION, OR RESISTANCE TO VANCOMYCIN, OR (C) PATIENT HAS A SKIN AND SKIN STRUCTURE INFECTION, INCLUDING DIABETIC FOOT INFECTIONS, CAUSED BY A SUSCEPTIBLE BACTERIA, AND ONE OF THE FOLLOWING: (I) AN INADEQUATE RESPONSE, MEDICAL CONTRAINDICATION, OR RESISTANCE TO TWO OF THE FOLLOWING: BETA-LACTAMS, MACROLIDES, CLINDAMYCIN, TETRACYCLINES, OR CO-TRIMOXAZOLE, OR (II) AN INADEQUATE RESPONSE, MEDICAL CONTRAINDICATION, OR RESISTANCE TO VANCOMYCIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, TRANSPLANT SPECIALIST, HEMATOLOGIST, OR ONCOLOGIST.

COVERAGE DURATION
THREE MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

LIVTENCITY

MEDICATION(S)
LIVTENCITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH GANCICLOVIR, VALGANCICLOVIR, FOSCARNET OR CIDOFOVIR.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) OR SOLID ORGAN TRANSPLANT (SOT) AND THE PATIENT HAS ACTIVE CYTOMEGALOVIRUS (CMV) INFECTION AND THE FOLLOWING: MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO GANCICLOVIR, CIDOFOVIR, FOSCARNET, OR VALGANCICLOVIR.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A TRANSPLANT OR INFECTIOUS DISEASE SPECIALIST, OR ONCOLOGIST.

COVERAGE DURATION
EIGHT WEEKS

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

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
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR SEVERE DIARRHEA-PREDOMINANT IRRITABE BOWEL SYNDROME (IBS), PATIENTS WITH (A) CHRONIC IBS SYMPTOMS FOR AT LEAST SIX MONTHS, AND (B) ANATOMIC OR BIOCHEMICAL ABNORMALITIES OF THE GASTROINTESTIONAL TRACT EXCLUDED, AND (C) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO CONVENTIONAL THERAPY (SUCH AS LOPERAMIDE), OR (3) IBS WITH SEVERE DIARRHEA. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

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

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) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, AND (3) HCV RNA LEVEL WITHIN PAST 6 MONTHS, AND (4) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: CARBAMAZEPINE, RIFAMPIN, ETHINYL ESTRADIOL-CONTAINING MEDICATION, ATAZANAVIR, DARUNAVIR, LOPINAVIR, RITONAVIR, EFAVIRENZ, ATORVASTATIN, LOVASTATIN, SIMVASTATIN, ROSUVASTATIN AT DOSES GREATER THAN 10MG, CYCLOSPORINE AT DOSES GREATER THAN 100MG PER DAY, EPCLUSA, HARVONI, VOSEVI, OR ZEPATIER, AND (5) PATIENT MUST NOT HAVE PRIOR FAILURE OF A DAA REGIMEN WITH NS5A INHIBITOR AND HCV PROTEASE INHIBITOR, AND (6) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH 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

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

MAYZENT

MEDICATION(S)
MAYZENT

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 A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE. RENEWAL CRITERIA: (1) POSITIVE RESPONSE TO THERAPY, AND (2) PATIENT DOES NOT HAVE LYMPHOPENIA.

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

MECASERMIN

MEDICATION(S)
INCRELEX

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 GROWTH FAILURE PATIENTS WITH SEVERE PRIMARY IGF-1 DEFICIENCY OR GROWTH HORMONE (GH) GENE DELETION WHO HAVE DEVELOPED NEUTRALIZING ANTIBODIES TO GH, AND (3) SEVERE PRIMARY IGF-1 DEFICIENCY DEFINED AS: (A) HEIGHT STANDARD DEVIATION SCORE LESS THAN OR EQUAL TO 3.0, AND (B) BASAL IGF-1 STANDARD DEVIATION SCORE LESS THAN OR EQUAL TO 3.0. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MELANOMA NP COMBO

MEDICATION(S)
BRAFTOVI, MEKINIST, MEKTOVI, TAFINLAR

PA INDICATION INDICATOR
3 - All Medically-Accepted 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) GENETIC TESTING HAS BEEN COMPLETED, IF REQUIRED, FOR THERAPY WITH THE REQUESTED AGENT AND RESULTS INDICATE THE REQUESTED AGENT IS APPROPRIATE, AND (3) PATIENT DOES NOT HAVE ANY FDA LABELED LIMITATIONS OF USE THAT IS NOT OTHERWISE SUPPORTED IN NCCN GUIDELINES, AND (4) ONE OF THE FOLLOWING: (A) THE REQUESTED AGENT IS FDA LABELED OR SUPPORTED BY COMPENDIA AS FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO THE FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (5) PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. FOR THE COMBINATION OF BRAFTOVI AND MEKTOVI OR TAFINLAR AND MEKINIST: (1) PATIENT HAS A DIAGNOSIS OF STAGE THREE MELANOMA, RECURRENT MELANOMA, OR METASTATIC MELANOMA AND (2) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ZELBORAF IN COMBINATION WITH COTELLIC.

PART B PREREQUISITE

N/A

METHOTREXATE SOLUTION

MEDICATION(S)
JYLAMVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR NEW START PATIENTS: 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

MIFEPRISTONE

MEDICATION(S)
MIFEPRISTONE 300 MG TABLET

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 ENDOGENOUS CUSHING'S DISEASE, PATIENT HAS (A) ONE OF THE FOLLOWING (I) DIAGNOSIS OF TYPE 2 DIABETES MELLITUS, OR (I) GLUCOSE INTOLERANCE AS DEFINED BY A 2-HOUR GLUCOSE TOLERANCE TEST PLASMA GLUCOSE VALUE OF 140-199 MG/DL, AND (B) PATIENT HAS FAILED SURGICAL RESECTION OR IS NOT A CANDIDATE FOR SURGICAL RESECTION. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.

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

MODAFINIL

MEDICATION(S)
MODAFINIL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER TARGET AGENT SUCH AS ARMODAFINIL.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR OBSTRUCTIVE SLEEP APNEA (OSA), DIAGNOSIS OF OSA DEFINED BY ONE OF THE FOLLOWING: (A) 15 OR MORE OBSTRUCTIVE RESPIRATORY EVENTS PER HOUR OF SLEEP CONFIRMED BY A SLEEP STUDY, UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, OR (B) BOTH OF THE FOLLOWING: (I) FIVE OR MORE OBSTRUCTIVE RESPIRATORY EVENTS PER HOUR OF SLEEP CONFIRMED BY A SLEEP STUDY, UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, AND (II) AT LEAST ONE OF THE FOLLOWING SYMPTOMS: DAYTIME SLEEPINESS, UNINTENTIONAL SLEEP EPISODES DURING WAKEFULNESS, UNREFRESHING SLEEP, FATIGUE, INSOMNIA, WAKING UP BREATH HOLDING/GASPING/CHOKING, LOUD SNORING, OR BREATHING INTERRUPTIONS DURING SLEEP, OR (3) FOR SHIFT-WORK DISORDER (SWD), DIAGNOSIS OF SWD CONFIRMED BY (A) ONE OF THE FOLLOWING: (I) PATIENT IS WORKING AT LEAST FIVE OVERNIGHT SHIFTS PER MONTH, OR (II) SLEEP STUDY DEMONSTRATING LOSS OF A NORMAL SLEEP-WAKE PATTERN SUCH AS DISTURBED CHRONOBIOLOGIC RHYTHMICITY, AND (B) NO OTHER MEDICAL CONDITIONS OR MEDICATIONS ARE CAUSING THE SYMPTOMS OF EXCESSIVE SLEEPINESS OR INSOMNIA, OR (4) FOR NARCOLEPSY CONFIRMED WITH POLYSOMNOGRAPHY AND A MULTIPLE SLEEP LATENCY TEST (MSLT), UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, OR (5) ADJUNCTIVE THERAPY FOR TREATMENT-RESISTANT DEPRESSION DEFINED AS MAJOR DEPRESSIVE DISORDER (MDD) OR BIPOLAR DEPRESSION, AND AN INTOLERANCE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANTS FROM DIFFERENT CLASSES (SUCH AS AN SSRI, SNRI, BUPROPION), OR (6) FOR IDIOPATHIC HYPERSOMNIA CONFIRMED BY A SLEEP STUDY,

UNLESS PRESCRIBER CONFIRMS A SLEEP STUDY IS NOT FEASIBLE, OR (7) MULTIPLE SCLEROSIS RELATED FATIGUE, OR (8) STEINERT MYOTONIC DYSTROPHY SYNDROME. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

MYFEMBREE

MEDICATION(S)
MYFEMBREE

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 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 PREPARATIONS (FOR EXAMPLE, ORAL OR VAGINAL CONTRACEPTIVES), (B) LEVONORGESTREL INTRA-UTERINE DEVICE (IUD), OR (C) ORAL TRANEXAMIC ACID, AND SURGICAL INTERVENTION HAS BEEN DISCUSSED AND IS NOT AN APPROPRIATE TREATMENT OPTION OR PATIENT DECLINES, OR (2) A DIAGNOSIS OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS, AND PATIENT HAS AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO (A) PRESCRIPTION STRENGTH NSAID OR CONTINUOUS ORAL CONTRACEPTIVE THERAPY OR PROGESTERONE THERAPY, AND (B) ORILISSA, AND SURGICAL INTERVENTION HAS BEEN DISCUSSED AND IS NOT AN APPROPRIATE TREATMENT OPTION OR PATIENT DECLINES. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN OB/GYN SPECIALIST.

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

NITAZOXANIDE

MEDICATION(S)
NITAZOXANIDE

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 DIARRHEA CAUSED BY GIARDIA LAMBLIA OR CRYPTOSPORIDIUM PARVUM.

AGE RESTRICTION
PATIENTS AGE 12 AND OLDER.

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

NITISINONE

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

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER NITISINONE PRODUCT.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF HEREDITARY TYROSINEMIA TYPE 1 (HT-1) CONFIRMED BY ELEVATED URINARY OR PLASMA SUCCINYLACETONE LEVELS OR A MUTATION IN THE FUMARYLACETOACETATE HYDROLASE GENE, AND (2) FOR ORFADIN SUSPENSION, PATIENT HAS DIFFICULTY SWALLOWING. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS URINARY OR PLASMA SUCCINYLACETONE LEVELS HAVE DECREASED FROM BASELINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEMATOLOGY, HEPATOLOGY, OR NEPHROLOGY.

COVERAGE DURATION
12 MONTHS

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

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) SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH) CAUSED BY ONE OF THE FOLLOWING: (A) PRIMARY AUTONOMIC FAILURE (SUCH AS PARKINSON'S DISEASE, MULTIPLE SYSTEM ATROPHY, OR PURE AUTONOMIC FAILURE), OR (B) DOPAMINE BETA-HYDROXYLASE DEFICIENCY, OR (C) NON-DIABETIC AUTONOMIC NEUROPATHY, AND (3) PATIENTS HAVE A DECREASE OF AT LEAST 20 MMHG IN SYSTOLIC OR 10 MMHG IN DIASTOLIC BLOOD PRESSURE WITHIN THREE MINUTES AFTER STANDING, AND (4) CONTRAINDICATIONS OR TRIAL AND FAILURE OF AT LEAST TWO FIRST LINE DRUG THERAPIES (FOR EXAMPLE FLUDROCORTISONE AND MIDODRINE). RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

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

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

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

PART B PREREQUISITE

N/A

NUBEQA

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC, METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (MHSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: NMCRPC, MHSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG.

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

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 MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE 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, OR (C) 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 LASTING 3 OR MORE DAYS 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, POSITIVE RESPONSE TO THERAPY. (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, IMMUNOLOGIST, 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
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) PATIENT HAS A STRUCTURAL NEUROLOGICAL CONDITION AS THE CAUSE OF PSEUDOBULBAR AFFECT. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

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

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 AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO TRIPTAN DRUGS (EXAMPLES SUMATRIPTAN, NARATRIPTAN, RIZATRIPTAN) OR (2) DIAGNOSIS OF EPISODIC MIGRAINE PREVENTION AND CONTRAINDICATIONS OR INADEQUATE RESPONSE TO AT LEAST TWO OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND PATIENT HAS GREATER THAN OR EQUAL TO 4 MIGRAINE DAYS PER MONTH. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
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

OFEV

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MUST NOT HAVE UNDERLYING LIVER DISEASE

REQUIRED MEDICAL INFORMATION
INITIAL: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR IDIOPATHIC PULMONARY FIBROSIS (IPF), (A) EXCLUSION OF OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (ILD) (SUCH AS ENVIRONMENTAL EXPOSURES, CONNECTIVE DISSUE DISEASE, DRUG TOXICITY), AND EITHER (I) PRESENCE OF HIGH-RESOLUTION CT (HRCT) PATTERN OF UNUSUAL INTERSTITIAL PNEUMONIA (UIP), OR (II) COMBINATIONS OF HRCT PATTERNS AND HISTOPATHOLOGY PATTERNS INDICATIVE OF IPF IN PATIENTS SUBJECT TO LUNG TISSUE SAMPLING, AND (B) FORCED VITAL CAPACITY (FVC) GREATER THAN OR EQUAL TO 50% AT BASELINE, AND (C) PERCENT PREDICTED DIFFUSING CAPACITY OF THE LUNGS FOR CARBON MONOXIDE (%DLCO) GREATER THAN OR EQUAL TO 30%, AND (D) INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO PIRFENIDONE, AND (3) FOR CHRONIC FIBROSING INTERSTITIAL LUNG DISEASES WITH PROGRESSIVE PHENOTYPE, (A) PATIENT HAS GREATER THAN 10% FIBROTIC FEATURES ON HRCT, AND CLINICAL SIGNS OF PROGRESSION DEFINED AS (I) FVC DECLINE GREATER THAN OR EQUAL TO 10%, OR (II) FVC DECLINE GREATER THAN OR EQUAL TO 5% AND WORSENING SYMPTOMS OR IMAGING IN THE PAST 24 MONTHS, AND (B) FVC GREATER THAN OR EQUAL TO 45% AT BASELINE, AND (C) PERCENT PREDICTED DIFFUSING CAPACITY OF THE LUNGS FOR CARBON MONOXIDE (%DLCO) GREATER THAN OR EQUAL TO 30%, AND (4) FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD), (A) PATIENT HAS EARLY DIFFUSE SSC AND ILD, AND (B) INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO MYCOPHENOLATE. RENEWAL: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR PULMONOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

MEDICATION(S)

AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AVMAPKI, AVMAPKI-FAKZYNJA, AYVAKIT, BALVERSA, BESREMI, BEXAROTENE, BOSULIF, CABOMETYX, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, DANZITEN, DASATINIB, DAURISMO, ERIVEDGE, ERLOTINIB HCL, EULEXIN, 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, FAKZYNJA, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GLEOSTINE, GOMEKLI, HERNEXEOS, IBTROZI, ICLUSIG, IDHIFA, IMKELDI, INLYTA, INREBIC, ITOVEBI, IWILFIN, JAKAFI, JAYPIRCA, KOSELUGO, KRAZATI, LAPATINIB, LAZCLUZE, LENVIMA, LEUPROLIDE DEPOT, LONSURF, LORBRENA, LUMAKRAS, LUPRON DEPOT, LYNPARZA, LYTGOBI, MATULANE, METFORMIN HCL 1,000 MG TABLET (GENERIC FOR GLUCOPHAGE), METFORMIN HCL 500 MG TABLET (GENERIC FOR GLUCOPHAGE), MODEYSO, NERLYNX, NILUTAMIDE, NINLARO, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, OPDIVO QVANTIG, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY, POMALYST, POTASSIUM CL ER 20 MEQ TABLET (DISSOLVABLE TABLET), QINLOCK, RETEVMO, REVUFORJ, REZLIDHIA, ROMVIMZA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB, STIVARGA, SUNITINIB MALATE, TABRECTA, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TECENTRIQ HYBREZA, TEPMETKO, TIBSOVO, TOREMIFENE CITRATE, TORPENZ, TRELSTAR, TRUQAP, TUKYSA, TURALIO, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, WELIREG, XOSPATA, XPOVIO, ZEJULA 100 MG TABLET, ZEJULA 200 MG TABLET, ZEJULA 300 MG TABLET, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

PA INDICATION INDICATOR

3 - All Medically-Accepted 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) GENETIC TESTING HAS BEEN COMPLETED, IF REQUIRED, FOR THERAPY WITH THE REQUESTED AGENT AND RESULTS INDICATE THE REQUESTED AGENT IS APPROPRIATE, AND (3) PATIENT DOES NOT HAVE ANY FDA LABELED LIMITATIONS OF USE THAT IS NOT OTHERWISE SUPPORTED IN NCCN GUIDELINES, AND (4) ONE OF THE FOLLOWING: (A) THE REQUESTED AGENT IS FDA LABELED OR SUPPORTED BY COMPENDIA AS FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO THE FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (5) PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

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

OPSUMIT

MEDICATION(S)
OPSUMIT

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 GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: (A) MEAN PULMONARY ARTERY PRESSURE (PAP) EQUAL TO OR GREATER THAN 20 MMHG, (B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF EQUAL TO OR LOWER THAN 15 MMHG, AND (C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

ORAL DISSOLVE TABLETS PROTECTED CLASS

MEDICATION(S)
ARIPIPRAZOLE ODT, CLOZAPINE ODT, LAMOTRIGINE ODT, OLANZAPINE 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) 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, RALDESY, TOPIRAMATE 25 MG/ML SOLUTION, 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) 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

ORGOVYX

MEDICATION(S)
ORGOVYX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA
LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. FOR ORGOVYX, (1) PATIENT HAS PROSTATE CANCER WITHOUT CARDIAC RISK FACTORS, AND (2) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO A GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (PART B BEFORE PART D STEP THERAPY - APPLIES ONLY TO BENEFICIARIES ENROLLED IN AN MA-PD PLAN).

PART B PREREQUISITE
YES

ORIAHNN

MEDICATION(S)
ORIAHNN

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 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 MENSTRUAL BLEEDING. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED 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 FDA-APPROVED LABELING, INCLUDING APPROPRIATE LIMITS ON TOTAL DURATION OF THERAPY.

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) FOR A DIAGNOSIS OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS, PATIENT HAS AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO (A) PRESCRIPTION STRENGTH NSAID, AND (B) CONTINUOUS ORAL CONTRACEPTIVE THERAPY OR PROGESTERONE THERAPY, AND (3) SURGICAL INTERVENTION HAS BEEN DISCUSSED AND IS NOT AN APPROPRIATE TREATMENT OPTION OR PATIENT DECLINES. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
PATIENTS AGE 18 YEARS AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH OBSTETRICS/GYNECOLOGY.

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

ORKAMBI

MEDICATION(S)
ORKAMBI

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. MAY NOT USE CONCURRENTLY WITH ANOTHER CFTR MODULATOR AGENT FOR THE REQUESTED INDICATION.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CYSTIC FIBROSIS, AND (2) PATIENT IS HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH 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

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 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 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 AND MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OR MORE CONSERVATIVE TREATMENTS (FOR EXAMPLE, COLCHICINE, TOPICAL CORTICOSTEROID, ORAL CORTICOSTEROID). RENEWAL CRITERIA: 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) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO 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 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, APREPITANT, AZATHIOPRINE 50 MG TABLET, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CLINISOL, CROMOLYN 20 MG/2 ML NEB SOLN, 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 2.5 MG TABLET, 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 15 MG/5 ML SYRUP, 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, RABAVERT, RECOMBIVAX HB, 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

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, HCV GENOTYPE, VIRAL LOAD AND LIVER FUNCTION TESTS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, OR HEPATOLOGIST, 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-APPROVED LABELING.

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 AFTER TREATMENT WITH POTASSIUM CITRATE AND CAPTOPRIL, OR MEDICAL CONTRAINDICATION TO THEIR USE, OR (2) WILSON'S DISEASE, OR (3) RHEUMATOID ARTHRITIS. RENEWAL CRITERIA: PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 12 MONTHS AND POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST, NEPHROLOGIST OR RHEUMATOLOGIST.

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) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE GENERIC ALPHA-BLOCKER, SUCH AS DOXAZOSIN.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PIRFENIDONE

MEDICATION(S)
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) PATIENT DOES NOT HAVE UNDERLYING LIVER DISEASE, AND (3) FOR IDIOPATHIC PULMONARY FIBROSIS (IPF), (A) DIAGNOSIS CONFIRMED BY EXCLUSION OF OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (ILD) (SUCH AS ENVIRONMENTAL EXPOSURES, CONNECTIVE DISSUE DISEASE, DRUG TOXICITY), AND EITHER (I) PRESENCE OF HIGH-RESOLUTION CT (HRCT) PATTERN OF UNUSUAL INTERSTITIAL PNEUMONIA (UIP), OR (II) COMBINATIONS OF HRCT PATTERNS AND HISTOPATHOLOGY PATTERNS INDICATIVE OF IPF IN PATIENTS SUBJECT TO LUNG TISSUE SAMPLING, AND (B) FORCED VITAL CAPACITY (FVC) IS GREATER THAN OR EQUAL TO 50% AT BASELINE, AND (C) PATIENT HAS A PERCENT PREDICTED DIFFUSING CAPACITY OF THE LUNGS FOR CARBON MONOXIDE (%DLCO) GREATER THAN OR EQUAL TO 30%. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

PLEGRIDY

MEDICATION(S)
PLEGRIDY, PLEGRIDY PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

POSACONAZOLE

MEDICATION(S)
POSACONAZOLE DR 100 MG TABLET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) FOR, PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS, REQUESTED AGENT IS PRESCRIBED FOR PATIENTS WHO ARE SEVERELY IMMUNOCOMPROMISED, SUCH AS A HEMATOPOIETIC STEM CELL TRANSPLANT [HSCT] RECIPIENTS, OR PATEINTS WITH HEMATOLOGIC MALIGNANCY WITH PROLONGED NEUTROPENIA FROM CHEMOTHERAPY, OR ARE HIGH-RISK SOLID ORGAN (LUNG, HEART-LUNG, LIVER, PANCREAS, SMALL BOWEL) TRANSPLANT PATIENTS, OR HAVE LONG TERM USE OF HIGH DOSE CORTICOSTEROIDS (GREATER THAN 1 MG/KG/DAY OF PREDNISONE OR EQUIVALENT), AND (2) FOR INVASIVE ASPERGILLUS, AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO VORICONAZOLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH INFECTIOUS DISEASE, PULMONOLOGY, HEMATOLOGY/ONCOLOGY OR ORGAN TRANSPLANTATION SPECIALISTS.

COVERAGE DURATION
THREE MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PROMACTA

MEDICATION(S)
ELTROMBOPAG OLAMINE

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) FOR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP), (A) BASELINE PLATELET COUNT IS LESS THAN 50,000/MM3, AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO CORTICOSTEROIDS (SUCH AS PREDNISONE), IMMUNOGLOBULINS (SUCH AS GAMMAGARD LIQUID, BIVIGAM), OR SPLENECTOMY, OR (3) FOR SEVERE APLASTIC ANEMIA, (A) BASELINE PLATELET COUNT IS LESS THAN 50,000/MM3, AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO, OR WILL BE USED CONCURRENTLY WITH CYCLOSPORINE OR GLUCOCORTICOIDS (SUCH AS DEXAMETHASONE), OR (4) FOR CHRONIC HEPATITIS C THROMBOCYTOPENIA, (A) CONTINUATION OR INITIATION OF INTERFERON BASED THERAPY IS CONTRAINDICATED DUE TO THOMBOCYTOPENIA, AND (B) BASELINE PLATELET COUNT IS LESS THAN 75,000/MM3. RENEWAL CRITERIA: (1) THE PATIENT HAS A POSITIVE CLINICAL RESPONSE TO THERAPY, AND (2) FOR CHRONIC HEPATITIS C THROMBOCYTOPENIA, PATIENT CONTINUES TO REQUIRE INTERFERON BASED THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR HEPATOLOGIST.

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

PULMOZYME

MEDICATION(S)
PULMOZYME

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. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A SPECIALIST FROM A CYSTIC FIBROSIS TREATMENT CENTER OR A PULMONOLOGIST.

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

PYRIMETHAMINE

MEDICATION(S)
PYRIMETHAMINE

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. FOR TOXOPLASMOSIS. RENEWAL: ONE OF THE FOLLOWING: (1) PERSISTENT CLINICAL DISEASE (HEADACHE, NEUROLOGICAL SYMPTOMS, OR FEVER) AND PERSISTENT RADIOGRAPHIC DISEASE (ONE OR MORE MASS LESIONS ON BRAIN IMAGING), OR (2) CD4 COUNT LESS THAN 200 CELLS/MM3 AND CURRENTLY TAKING AN ANTI-RETROVIRAL THERAPY IF HIV POSITIVE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
TOXOPLASMOSIS INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.

COVERAGE DURATION
INITIAL: 8 WEEKS, RENEWAL: 6 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: (1) DIAGNOSIS OF HEMOLYTIC ANEMIA CONFIRMED BY THE PRESENCE OF CHRONIC HEMOLYSIS (SUCH AS INCREASED INDIRECT BILIRUBIN) WITH PYRUVATE KINASE (PK) DEFICIENCY CONFIRMED BY MOLECULAR TESTING OF THE FOLLOWING MUTATIONS IN THE PYRUVATE KINASE LIVER AND RED BLOOD CELL (PKLR) GENE: (A) PRESENCE OF AT LEAST TWO VARIANT ALLELES OF WHICH AT LEAST ONE WAS A MISSENSE VARIANT, AND (B) NOT HOMOZYGOUS FOR THE C.1436G TO A (P.R479H) VARIANT, AND (C) DOES NOT HAVE 2 NON-MISSENSE VARIANTS (WITHOUT PRESENCE OF ANOTHER MISSENSE VARIANT), AND (2) PATIENT HAS A HEMOGLOBIN LESS THAN OR EQUAL TO 10 G/DL, AND (3) PATIENT HAS SYMPTOMATIC ANEMIA OR IS TRANFUSION DEPENDENT. RENEWAL CRITERIA: 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
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST.

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

RASUVO

MEDICATION(S)
RASUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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) 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

REBIF

MEDICATION(S)
REBIF, REBIF REBIDOSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

RETACRIT

MEDICATION(S)
RETACRIT

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 CHRONIC KIDNEY DISEASE (CKD) OR ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL OF LESS THAN 10G/DL, AND (3) FOR ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL LESS THAN 13G/DL. RENEWAL CRITERIA: (1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS, OR (2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS, OR (3) ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL, OR (4) CANCER CHEMOTHERAPY: 1) HEMOGLOBIN LEVEL OF LESS THAN 10 G/DL, OR 2) THE HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE: INITIAL/RENEWAL: 12 MONTHS.

SURGERY:1 MONTH.

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

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 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
PRESCRIBED 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. NO EXCLUSION CRITERIA FOR ATOPIC DERMATITIS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: DIAGNOSIS OF: (1) MODERATE TO SEVERE RHEUMATOID ARTHRITIS WITH 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) POLYARTICULAR JUVENILE IDIOPATHIC 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) MODERATE TO SEVERE ATOPIC DERMATITIS WITH AT LEAST 10% BODY SURFACE AREA (BSA) OR INVOLVEMENT WITH THE FACE, NECK, HANDS, FEET, GENITALS OR INTERTRIGINOUS AREAS, AND (II) INTRACTABLE PRURITUS OR CRACKING/OOZING/BLEEDING OF AFFECTED SKIN, AND (III) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID OR ONE TOPICAL CALCINEURIN INHIBITOR (SUCH AS TACROLIMUS, PIMECROLIMUS), OR (4) MODERATE TO SEVERE ULCERATIVE COLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: HUMIRA OR HADLIMA, OR (5) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO: (1) TREATMENT WITH ONE NSAID FOR ONE MONTH, AND FOR PERIPHERAL DISEASE ONLY, MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE WITH ONE OF THE FOLLOWING: LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), 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 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 DISEASE, OR (II) 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, OR (8) ACTIVE PSORIATIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: HUMIRA, HADLIMA, OR ENBREL. RENEWAL CRITERIA: TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

PART B PREREQUISITE
N/A

RUCONEST

MEDICATION(S)
RUCONEST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER HAE AGENT INDICATED FOR TREATMENT OF ACUTE HAE ATTACKS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA (HAE), DIAGNOSIS CONFIRMED BY TWO CONFIRMATORY TESTS OF C1-INH ANTIGENIC LEVEL, C1-INH FUNCTIONAL LEVEL, AND C4 LEVEL AS FOLLOWS: (A) TYPE I DEFINED AS DECREASED QUANTITIES OF C4 AND C1 INHIBITOR (C1INH), OR (B) TYPE II DEFINED AS DECREASED QUANTITIES OF FUNCTIONAL C1INH, OR (C) A KNOWN-HAE CAUSING C1INH MUTATION SUCH AS A FACTOR XII MUTATION, ANGIOPOIETIN-1 (ANGPT1) MUTATION, PLASMINOGEN (PLG) MUTATION, KININOGEN1 MUTATION, HEPARAN SULFATE 3-O-SULFOTRANSFERASE 6 GENE MUTATION, OR MYOFERLIN GENE MUTATION, AND (3) MEDICATIONS KNOWN TO CAUSE ANGIOEDEMA (SUCH AS ESTROGENS, ACE INHIBITORS, ANGIOTENSIN II BLOCKERS) HAVE BEEN EVALUATED AND DISCONTINUED WHEN APPROPRIATE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS A DECREASE IN THE FREQUENCY OR SEVERITY OF ACUTE ATTACKS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.

COVERAGE DURATION
12 MONTHS

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

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: 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
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

SAPROPTERIN

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

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 THE DIAGNOSIS OF TETRAHYDROBIOPTERIN-(BH4-) RESPONSIVE PHENYLKETONURIA (PKU), PATIENT HAS A BASELINE BLOOD PHE LEVEL MEASURED PRIOR TO INITIATION OF THERAPY WITH THE REQUESTED AGENT, WHICH IS ABOVE THE RECOMMENDED LEVELS INDICATED FOR THE PATIENT'S AGE RANGE OR CONDITION. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) PATIENT'S BLOOD PHE LEVELS ARE BEING MAINTAINED WITHIN THE ACCEPTABLE RANGE OR PATIENT HAS HAD A DECREASE IN BLOOD PHE LEVEL FROM BASELINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH 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

SAVELLA

MEDICATION(S)
SAVELLA

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 FIBROMYALGIA, MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO TWO OF THE FOLLOWING: GABAPENTIN, PREGABALIN, OR DULOXETINE.

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
PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY. USE FOR ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR HIV-INFECTED PATIENTS DIAGNOSED WITH SIGNIFICANT WASTING, MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE OR MORE CONVENTIONAL THERAPY (E.G., MEGESTROL, APPETITE STIMULANTS, ANABOLIC STEROIDS), AND (3) PATIENT WILL BE USING CONCOMITANT ANTIRETROVIRAL THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A PRACTITIONER WITH EXPERIENCE IN THE DIAGNOSIS AND MANAGEMENT OF HIV INFECTION.

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
PATIENT MUST NOT HAVE SEVERE HEPATIC IMPAIRMENT.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DIAGNOSIS OF ENDOGENOUS CUSHING'S DISEASE (MEANING HYPERCORTISOLISM IS NOT FROM CHRONIC HIGH DOSE GLUCOCORTICOIDS), AND (3) PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE. RENEWAL CRITERIA: (1) PATIENT HAS A REDUCTION IN MEAN URINARY FREE CORTISOL LEVEL AND A POSITIVE CLINICAL RESPONSE TO THERAPY.

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
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS A DIAGNOSIS OF WHO GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH) 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. RENEWAL CRITERIA: (1) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY INCLUDING BUT NOT LIMITED TO IMPROVED HEMODYNAMIC STATUS, IMPROVED FUNCTIONAL CAPACITY, OR REDUCTION IN HOSPITALIZATIONS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

SIRTURO

MEDICATION(S)
SIRTURO

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 PULMONARY MULTIDRUG RESISTANT TUBERCULOSIS (MDR-TB), WITH ADVERSE REACTIONS OR RESISTANCE TO STANDARD DRUGS USED TO TREAT MDR-TB, AND (A) USED IN COMBINATION WITH AT LEAST THREE OTHER MEDICATIONS TO WHICH THE PATIENT'S MDR-TB ISOLATE HAS BEEN SHOWN TO BE SUSCEPTIBLE IN VITRO, OR (B) USED IN COMBINATION WITH AT LEAST FOUR OTHER MEDICATIONS TO WHICH THE PATIENT'S MDR-TB ISOLATE IS LIKELY TO BE SUSCEPTIBLE IF IN VITRO RESULTS ARE UNAVAILABLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.

COVERAGE DURATION
24 WEEKS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SIVEXTRO

MEDICATION(S)
SIVEXTRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH LINEZOLID FOR THE SAME INFECTION.

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI) DEFINED AS A BASELINE LESION SIZE OF 75 CM2, AND (3) USE IN INFECTIONS THAT ARE PROVEN OR STRONGLY SUSPECTED TO BE CAUSED BY SUSCEPTIBLE BACTERIA.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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) ACTIVE PSORIATIC ARTHRITIS, OR (3) CROHN'S DISEASE WITH: (I) FISTULIZING DISEASE, OR (II) 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, OR (4) MODERATE TO SEVERE ULCERATIVE COLITIS. RENEWAL CRITERIA: 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

SODIUM OXYBATE

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.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF CATAPLEXY ASSOCIATED WITH NARCOLEPSY CONFIRMED WITH POLYSOMNOGRAPHY (PSG), MULTIPLE SLEEP LATENCY TESTING (MSLT), OR CEREBROSPINAL FLUID ANALYSIS THAT SUPPORTS THE DIAGNOSIS, 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) SUNOSI (SUNOSI IS NOT REQUIRED FOR PATIENTS LESS THAN 18 YEARS OF AGE), OR (2) DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY, CONFIRMED WITH POLYSOMNOGRAPHY (PSG), MULTIPLE SLEEP LATENCY TESTING (MSLT), OR CEREBROSPINAL FLUID ANALYSIS THAT SUPPORTS THE DIAGNOSIS, AND THE PATIENT HAS A MEDICAL CONTRAINDICATION OR NO IMPROVEMENT IN SYMPTOMS DESPITE ONE MONTH OF TREATMENT WITH TWO OF THE FOLLOWING THERAPIES: (A) A SLEEP DISORDER AGENT TO REDUCE DAYTIME SLEEPINESS (SUCH AS MODAFINIL OR ARMODAFINIL) AND, (B) SUNOSI (SUNOSI IS 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) POSITIVE RESPONSE TO THERAPY, SUCH AS REDUCTION IN SYMPTOMS OF DAYTIME SLEEPINESS OR REDUCTION IN FREQUENCY OF CATAPLEXY ATTACKS.

AGE RESTRICTION
PATIENTS AGE 7 AND OLDER.

PRESCRIBER RESTRICTION

PRESCRIBED BY A PROVIDER EXPERIENCED IN THE MANAGEMENT OF NARCOLEPSY INCLUDING BUT NOT LIMITED TO, NEUROLOGISTS AND SLEEP SPECIALISTS.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

SODIUM PHENYLBUTYRATE

MEDICATION(S)
SODIUM PHENYLBUTYRATE POWDER

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) FOR UREA CYCLE DISORDERS WITH DEFICIENCIES OF CARBAMYLPHOSPHATE SYNTHETASE, ORNITHINE TRANSCARBAMYLASE, OR ARGININOSUCCINIC ACID SYNTHETASE AND ONE OF THE FOLLOWING (A) NEONATAL-ONSET DEFICIENCIES (COMPLETE ENZYMATIC DEFICIENCY), OR (B) LATE-ONSET DISEASE (PARTIAL ENZYMATIC DEFICIENCY, PRESENTING AFTER THE FIRST MONTH OF LIFE) WHO HAVE A HISTORY OF HYPERAMMONEMIC ENCEPHALOPATHY. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM.

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
INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTIAGING PURPOSES.

REQUIRED MEDICAL INFORMATION
INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), TURNER SYNDROME (TS), NOONAN SYNDROME: HEIGHT AT LEAST 2 STANDARD DEVIATIONS (SD) BELOW THE MEAN HEIGHT FOR NORMAL CHILDREN OF THE SAME AGE AND GENDER. PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
INITIAL: ADULT GHD: GROWTH HORMONE DEFICIENCY ALONE OR ASSOCIATED WITH MULTIPLE HORMONE DEFICIENCIES (HYPOPITUITARISM), AS A RESULT OF PITUITARY DISEASES, HYPOTHALAMIC DISEASE, SURGERY, RADIATION THERAPY, TRAUMA, OR CONTINUATION OF THERAPY FROM CHILDHOOD ONSET GROWTH HORMONE DEFICIENCY. PEDIATRIC GHD, ISS, SGA, TS, NOONAN SYNDROME: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. RENEWAL: PEDIATRIC GHD: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2)

OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR PATIENT HAS NOT COMPLETED PREPUBERTAL GROWTH. ISS, SGA, TS, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PWS: IMPROVEMENT IN BODY COMPOSITION.

PART B PREREQUISITE

N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

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 TREATMENT OF ACROMEGALY, AND (A) DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: (I) SERUM GROWTH HORMONE (GH) LEVEL GREATER THAN 1 NG/ML AFTER A TWO HOUR ORAL GLUCOSE TOLERANCE TEST (OGTT), OR (II) ELEVATED SERUM IGF-1 LEVELS, AND (B) AN INADEQUATE RESPONSE TO SURGERY OR RADIATION THERAPY, OR FOR WHOM THESE THERAPIES ARE NOT APPROPRIATE, AND (C) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO OCTREOTIDE. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY

AGE RESTRICTION
N/A

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

STELARA

MEDICATION(S)
SELARSDI, STELARA, YESINTEK

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 DISEASE, OR (II) 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) ACTIVE PSORIATIC ARTHRITIS, OR (4) MODERATE TO SEVERE ULCERATIVE COLITIS. RENEWAL CRITERIA: 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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS AN INADEQUATE CONTROL ON CLOBAZAM, AND (3) USED IN COMBINATION WITH CLOBAZAM, AND (4) BASELINE NEUTROPHIL AND PLATELET COUNTS ARE WITHIN NORMAL LIMITS. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) NEUTROPHIL AND PLATELET COUNTS ARE WITHIN NORMAL LIMITS, AND (3) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

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

SUCRAID

MEDICATION(S)
SUCRAID

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 CONGENITAL SUCROSE-ISOMALTASE DEFICIENCY (CSID). RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE PAST 12 MONTHS, AND (2) POSTIVE RESPONSE TO THERAPY SUCH AS A REDUCTION IN BREATH HYDROGEN EXCRETION OR, FEWER AND/OR MORE FORMED STOOLS COMPARED TO BASELINE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A PROVIDER SPECIALIZING IN GENETICS, METABOLIC DISORDERS, OR GASTROENTEROLOGY.

COVERAGE DURATION
TWO 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
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
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 (A) FOR EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY, OR (B) OBSTRUCTIVE SLEEP APNEA (OSA), AND (2) TRIAL AND FAILURE OR CONTRAINDICATION TO MODAFINIL OR ARMODAFINIL. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PROVIDER IN THE PAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A SLEEP SPECIALIST OR A NEUROLOGIST.

COVERAGE DURATION
12 MONTHS

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

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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS A DIAGNOSIS OF WHO GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH) 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. RENEWAL CRITERIA: (1) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY INCLUDING BUT NOT LIMITED TO IMPROVED HEMODYNAMIC STATUS, IMPROVED FUNCTIONAL CAPACITY, OR REDUCTION IN HOSPITALIZATIONS.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

TADALAFIL BPH

MEDICATION(S)
TADALAFIL 5 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 AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND FOR TREATMENT OF BENIGN PROSTATIC HYPERPLASIA (BPH). RENEWAL CRITERIA: POSITIVE RESPONSE TO 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

TAKHZYRO

MEDICATION(S)
TAKHZYRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MAY NOT USE CONCURRENTLY WITH ANOTHER HAE AGENT INDICATED FOR PROPHYLAXIS OF HAE ATTACKS.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR PROPHYLAXIS OF HEREDITARY ANGIOEDEMA (HAE) ATTACKS, DIAGNOSIS CONFIRMED BY TWO CONFIRMATORY TESTS OF C1-INH ANTIGENIC LEVEL, C1-INH FUNCTIONAL LEVEL, AND C4 LEVEL AS FOLLOWS: (A) TYPE I DEFINED AS C4 LESS THAN 14 MG/DL AND C1 INHIBITOR (C1INH) LESS THAN 19.9 MG/DL, OR (B) TYPE II DEFINED AS FUNCTIONAL C1INH LESS THAN 72%, OR (C) A KNOWN-HAE CAUSING C1INH MUTATION SUCH AS A FACTOR XII MUTATION, ANGIOPOIETIN-1 (ANGPT1) MUTATION, PLASMINOGEN (PLG) MUTATION, KININOGEN1 MUTATION, HEPARAN SULFATE 3-O-SULFOTRANSFERASE 6 GENE MUTATION, OR MYOFERLIN GENE MUTATION, AND (3) MEDICATIONS KNOWN TO CAUSE ANGIOEDEMA (SUCH AS ESTROGENS, ACE INHIBITORS, ANGIOTENSIN II BLOCKERS) HAVE BEEN EVALUATED AND DISCONTINUED WHEN APPROPRIATE, AND (4) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO DANAZOL. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY SUCH AS A DECREASE IN THE FREQUENCY OR SEVERITY OF HAE ATTACKS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST.

COVERAGE DURATION
SIX MONTHS

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

PART B PREREQUISITE
N/A

TALICIA

MEDICATION(S)
TALICIA

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 TREATMENT OF HELICOBACTER PYLORI INFECTION, AND (3) USE IN INFECTIONS THAT ARE PROVEN OR STRONGLY SUSPECTED TO BE CAUSED BY SUSCEPTIBLE BACTERIA, AND (4) FOR PATIENTS WHO HAVE MEDICAL 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

TAVNEOS

MEDICATION(S)
TAVNEOS

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, AND (1) FOR SEVERE ACTIVE ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY (ANCA)-ASSOCIATED VASCULITIS (GRANULOMATOSIS WITH POLYANGIITIS [GPA] AND MICROSCOPIC POLYANGIITIS [MPA]) IN COMBINATION WITH GLUCOCORTICOID THERAPY, AND (A) DIAGNOSIS CONFIRMED BY CLINICAL FINDINGS (SUCH AS SMALL VESSEL VASCULITIS OF THE EAR, NOSE, THROAT, AIRWAYS, LUNGS, KIDNEYS, SKIN, EYES, OR PERIPHERAL NERVOUS SYSTEM), LABORATORY TEST (POSITIVE FOR ANCA [MPO OR PR3 SUBTYPES]), AND IMAGING STUDIES, AND (B) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO AT LEAST ONE OF THE FOLLOWING FOR 12 WEEKS: CYCLOPHOSPHAMIDE, METHOTREXATE, AZATHIOPRINE, OR MYCOPHENOLATE MOFETIL. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS, AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

PART B PREREQUISITE

N/A

THIOLA

MEDICATION(S)
TIOPRONIN 100 MG TABLET

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) HOMOZYGOUS CYSTINURIA AND URINARY CYSTINE GREATER THAN 500MG/DAY AFTER TREATMENT WITH POTASSIUM CITRATE AND CAPTOPRIL, OR MEDICAL CONTRAINDICATION TO THEIR USE. RENEWAL CRITERIA: (1) THE PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 12 MONTHS AND (2) PATIENT HAS A POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A UROLOGIST OR NEPHROLOGIST.

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

TRANSMUCOSAL FENTANYL

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) FOR BREAKTHROUGH, CHRONIC CANCER PAIN IN PATIENTS WITH ACTIVE CANCER, AND (3) THE PATIENT HAS DIFFICULTY SWALLOWING, ESOPHAGITIS, MUCOSITIS, DYSPHAGIA, UNCONTROLLABLE NAUSEA/VOMITING, OR HAS COMPLIANCE CONCERNS WITH ORAL NARCOTIC TABLETS, CAPSULES, OR LIQUID, AND (4) PATIENT IS CURRENTLY BEING TREATED WITH A LONG-ACTING OPIOID WITH THE REQUESTED AGENT WITHIN THE PAST 90 DAYS, AND (5) PATIENT HAS AT LEAST A ONE WEEK HISTORY OF ONE OF THE FOLLOWING AROUND-THE-CLOCK MEDICATIONS TO DEMONSTRATE TOLERANCE TO OPIOIDS: (A) AT LEAST 60 MG OF ORAL MORPHINE PER DAY, OR (B) AT LEAST 25 MCG OF TRANSDERMAL FENTANYL PER HOUR, OR (C) AT LEAST 30 MG OF ORAL OXYCODONE PER DAY, OR (D) AT LEAST 8 MG OF ORAL HYDROMORPHONE PER DAY, OR (E) AT LEAST 60 MG OF ORAL HYDROCODONE PER DAY, OR (F) AN EQUIANALGESIC DOSE OF ANOTHER OPIOID (SUCH AS ORAL METHADONE AT LEAST 20 MG PER DAY).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST, PAIN SPECIALIST, HEMATOLOGIST, HOSPICE CARE SPECIALIST, OR A PALLIATIVE CARE SPECIALIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

PART B PREREQUISITE

N/A

TREMFYA

MEDICATION(S)
TREMFYA, TREMFYA ONE-PRESS, TREMFYA PEN, TREMFYA PEN INDUCTION PK-CROHN

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) ACTIVE PSORIATIC ARTHRITIS, OR (3) MODERATE TO SEVERE ULCERATIVE COLITIS. RENEWAL CRITERIA: TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, GASTROENTEROLOGIST, 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 (HEPATOLENTICULAR DEGENERATION) CONFIRMED BY TWO OF THE FOLLOWING: (A) GENETIC MUTATION OF THE ATP7B GENE, OR (B) PRESENCE OF KAYSER-FLEISCHER RINGS, OR (C) PRESENCE OF NEUROLOGICAL SYMPTOMS, OR (D) PRESENCE OF HEPATIC ABNORMALITY, OR (E) SERUM CERULPLASMIN LEVEL LESS THAN 20 MG/DL, OR (F) BASAL URINARY COPPER EXCRETION GREATER THAN 40 MCG/24 HOURS, OR (G) HEPATIC PARENCHYMAL COPPER GREATER THAN 40 MCG/G DRY WEIGHT, AND (2) INTOLERANCE OR MEDICAL CONTRAINDICATION TO PENICILLAMINE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 12 MONTHS AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGIST, OR HEPATOLOGIST.

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

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 CONTINUES TO CLINICALLY BENEFIT FROM THERAPY (EXAMPLE, IMPROVED FEV1 OR REDUCTION IN PULMONARY EXACERBATIONS).

AGE RESTRICTION
PATIENTS AGE 2 AND OLDER.

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A 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 AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) ONE OF THE FOLLOWING: (A) USED IN THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AT HIGH RISK FOR FRACTURE OR MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO OTHER AVAILABLE OSTEOPOROSIS THERAPIES SUCH AS BISPHOSPHONATES, OR (B) USED IN THE TREATMENT TO INCREASE BONE DENSITY IN MEN WITH OSTEOPOROSIS AT HIGH RISK FOR FRACTURE OR MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO OTHER AVAILABLE OSTEOPOROSIS THERAPIES SUCH AS 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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS RECEIVED AT LEAST ONE PRIOR SKIN-DIRECTED THERAPY (SUCH AS TOPICAL CORTICOSTEROIDS, BEXAROTENE TOPICAL GEL). RENEWAL CRITERIA: 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

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) PATIENT HAS AN EJECTION FRACTION LESS THAN 45 PERCENT, AND (3) PATIENT HAS NEW YORK HEART ASSOCIATION (NYHA) CLASS II, III, OR IV SYMPTOMS, AND (4) EITHER ONE OF THE FOLLOWING: (A) AT LEAST 1 PRIOR HOSPITALIZATION FOR HEART FAILURE (HF) WITHIN THE LAST SIX MONTHS, OR (B) PATIENT HAS REQUIRED TREATMENT WITH OUTPATIENT INTRAVENOUS DIURETICS (SUCH AS FUROSEMIDE) WITHIN THE LAST 3 MONTHS, AND (5) 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), OR (D) SGLT-2 INHIBITOR (SUCH AS JARDIANCE, SYNJARDY). RENEWAL CRITERIA: (1) POSITIVE RESPONSE TO THERAPY AND (2) THE PATIENT HAS BEEN SEEN WITHIN THE LAST 14 MONTHS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

VERZENIO

MEDICATION(S)
VERZENIO

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: POSITIVE RESPONSE TO THERAPY.

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

VORICONAZOLE

MEDICATION(S)
VORICONAZOLE, VORICONAZOLE (HPBCD)

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 INVASIVE ASPERGILLUS, OR (2) PATIENT HAS A SERIOUS INFECTION CAUSED BY SCEDOSPORIUM APIOSPERMUM OR FUSARIUM SPECIES, OR (3) PATIENT HAS ESOPHAGEAL CANDIDIASIS OR CANDIDEMIA IN NON-NEUTROPENIC PATIENT AND MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO FLUCONAZOLE OR AN ALTERNATIVE ANTIFUNGAL AGENT.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, TRANSPLANT SPECIALIST, HEMATOLOGIST, OR ONCOLOGIST.

COVERAGE DURATION
ONE MONTH FOR ESOPHAGEAL CANDIDIASIS. SIX MONTHS FOR ALL OTHER INDICATIONS.

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) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, AND (3) HCV RNA LEVEL WITHIN PAST 6 MONTHS, AND (4) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, CYCLOSPORINE, PITAVASTATIN, PRAVASTATIN (DOSES ABOVE 40MG), ROSUVASTATIN, METHOTREXATE, MITOXANTRONE, IMATINIB, IRINOTECAN, LAPATINIB, SULFASALAZINE, TOPOTECAN, OR HIV REGIMEN THAT CONTAINS EFAVIRENZ, ATAZANAVIR, LOPINAVIR, TIPRANAVIR/RITONAVIR, SOVALDI (AS A SINGLE AGENT), EPCLUSA, HARVONI, ZEPATIER, OR MAVYRET, AND (5) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

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

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

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
(1) DIAGNOSIS OF RECURRENT CLOSTRIDIOIDES DIFFICILE INFECTION (CDI). RECURRENT CDI IS DEFINED AS THREE OR MORE PREVIOUS EPISODES TREATED WITH ANTIBIOTICS SUCH AS VANCOMYCIN, AND (2) PATIENT HAS COMPLETED THE ANTIBIOTIC THERAPY 2-4 DAYS PRIOR TO INITIATING VOWST AND HAS COMPLETED THE RECOMMENDED COURSE OF MAGNESIUM CITRATE THE DAY BEFORE AND AT LEAST 8 HOURS PRIOR TO INITIATING VOWST.

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

VUMERITY

MEDICATION(S)
VUMERITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
(1) DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, AND (2) MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO ONE OF THE FOLLOWING: TERIFLUNOMIDE, DIMETHYL FUMARATE, FINGOLIMOD, OR GLATIRAMER ACETATE.

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

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 (ATTR-CM), AND (2) DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: (A) CARDIAC BIOPSY WITH POSITIVE CONGO RED STAINING AND ATTR CONFIRMATION BY MASS SPECTROMETRY OR IMMUNOFLUORESCENCE STAINING, OR (B) ALL OF THE FOLLOWING: (I) SERUM KAPPA/LAMBDA FREE LIGHT CHAIN RATIO 0.26 TO 1.65, AND (II) ABSENCE OF MONOCLONAL PROTEIN VIA SERUM PROTEIN IMMUNOFIXATION, AND (III) ABSENCE OF MONOCLONAL PROTEIN VIA URINE PROTEIN IMMUNOFIXATION, AND (IV) MYOCARDIAL UPTAKE OF 99MTC-PYP DEMONSTRATED BY A GREATER THAN 1.5 HEART-TO-CONTRALATERAL RATIO OR GRADE 2 OR GREATER VISUAL EVIDENCE, AND (3) PATIENT HAS CLINICAL HISTORY OF HEART FAILURE (HF), WITH DOCUMENTATION OF EITHER OF THE FOLLOWING: (A) AT LEAST ONE PRIOR HOSPITALIZATION FOR HF, OR (B) CLINICAL SYMPTOMS OF CARDIOMYOPATHY AND HEART FAILURE (SUCH AS DYSPNEA, FATIGUE, ORTHOSTATIC HYPOTENSION, SYNCOPE, PERIPHERAL EDEMA), AND (4) PATIENT IS NEGATIVE FOR LIGHT CHAIN AMYLOIDOSIS, AND (5) PATIENT HAS NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THEIR PRESCRIBER IN THE PAST 12 MONTHS, AND (2) MEDICATION HAS DEMONSTRATED EFFICACY, AND (3) PATIENT CONTINUES TO HAVE NYHA CLASS I, II, OR III HEART FAILURE.

AGE RESTRICTION
PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.

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
MAY NOT USE VYNDAQEL CONCURRENTLY WITH ONPATTRO OR TEGSEDI.

REQUIRED MEDICAL INFORMATION
INITIAL CRITERIA: (1) PATIENT IS DIAGNOSED WITH WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS CARDIOMYOPATHY (ATTR-CM), AND (2) DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: (A) CARDIAC BIOPSY WITH POSITIVE CONGO RED STAINING AND ATTR CONFIRMATION BY MASS SPECTROMETRY OR IMMUNOFLUORESCENCE STAINING, OR (B) ALL OF THE FOLLOWING: (I) SERUM KAPPA/LAMBDA FREE LIGHT CHAIN RATIO 0.26 TO 1.65, AND (II) ABSENCE OF MONOCLONAL PROTEIN VIA SERUM PROTEIN IMMUNOFIXATION, AND (III) ABSENCE OF MONOCLONAL PROTEIN VIA URINE PROTEIN IMMUNOFIXATION, AND (IV) MYOCARDIAL UPTAKE OF 99MTC-PYP DEMONSTRATED BY A GREATER THAN 1.5 HEART-TO-CONTRALATERAL RATIO OR GRADE 2 OR GREATER VISUAL EVIDENCE, AND (3) PATIENT HAS CLINICAL HISTORY OF HEART FAILURE (HF), WITH DOCUMENTATION OF EITHER OF THE FOLLOWING: (A) AT LEAST ONE PRIOR HOSPITALIZATION FOR HF, OR (B) CLINICAL SYMPTOMS OF CARDIOMYOPATHY AND HEART FAILURE (SUCH AS DYSPNEA, FATIGUE, ORTHOSTATIC HYPOTENSION, SYNCOPE, PERIPHERAL EDEMA), AND (4) PATIENT IS NEGATIVE FOR LIGHT CHAIN AMYLOIDOSIS, AND (5) PATIENT HAS NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THEIR PRESCRIBER IN THE PAST 12 MONTHS, AND (2) MEDICATION HAS DEMONSTRATED EFFICACY, AND (3) PATIENT CONTINUES TO HAVE NYHA CLASS I, II, OR III HEART FAILURE.

AGE RESTRICTION
PATIENTS AGE 18 AND OLDER.

PRESCRIBER RESTRICTION

PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST.

COVERAGE DURATION
12 MONTHS

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

PART B PREREQUISITE
N/A

WYOST

MEDICATION(S)
WYOST

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) FOR PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA AND 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. RENEWAL CRITERIA: PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 14 MONTHS AND POSITIVE RESPONSE TO 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

XALKORI

MEDICATION(S)
XALKORI

PA INDICATION INDICATOR
3 - All Medically-Accepted 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) GENETIC TESTING HAS BEEN COMPLETED, IF REQUIRED, FOR THERAPY WITH THE REQUESTED AGENT AND RESULTS INDICATE THE REQUESTED AGENT IS APPROPRIATE, AND (3) PATIENT DOES NOT HAVE ANY FDA LABELED LIMITATIONS OF USE THAT IS NOT OTHERWISE SUPPORTED IN NCCN GUIDELINES, AND (4) ONE OF THE FOLLOWING: (A) THE REQUESTED AGENT IS FDA LABELED OR SUPPORTED BY COMPENDIA AS FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO THE FIRST-LINE THERAPY FOR THE REQUESTED INDICATION, OR (5) PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
SIX MONTHS

OTHER CRITERIA

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. FOR XALKORI: (1) PATIENT HAS A DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER, AND (A) PATIENT IS ALK POSITIVE, AND (B) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ALECENSA, OR (2) PATIENT HAS A DIAGNOSIS OF ROS1 POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER, OR (3) ANAPLASTIC LARGE CELL LYMPHOMA (ALCL), OR (4) INFLAMMATORY MYOFIBROBLASTIC TUMOR (IMT).

PART B PREREQUISITE

N/A

XATMEP

MEDICATION(S)
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: 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

XCOPRI

MEDICATION(S)
XCOPRI

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) MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE ANTI-SEIZURE MEDICATIONS SUCH AS LAMOTRIGINE, LEVETIRACETAM, OR TOPIRAMATE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED 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

XDEMVY

MEDICATION(S)
XDEMVY

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, AND FOR DEMODEX BLEPHARITIS. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN OPTOMETRIST OR OPHTHALMOLOGIST.

COVERAGE DURATION
SIX WEEKS

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

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 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 MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, AND RINVOQ, OR (3) ULCERATIVE COLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE STELARA, RINVOQ, SKYRIZI, TREMFYA, HADLIMA, AND HUMIRA, OR (4) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HADLIMA, AND HUMIRA, OR (5) ANKYLOSING SPONDYLITIS WITH MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO AT LEAST TWO PREFERRED DRUGS. PREFERRED DRUGS INCLUDE ENBREL, HUMIRA, HADLIMA, RINVOQ AND COSENTYX. RENEWAL CRITERIA: 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
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. RENEWAL CRITERIA: (1) PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 14 MONTHS AND (2) POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.

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

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), CONFIRMATION THAT IT IS CAUSED BY A SUSCEPTIBLE BACTERIA, AND (3) INADEQUATE RESPONSE OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS TO WHICH THE BACTERIA IS SUSCEPTIBLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN 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: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DIARRHEA IS INADEQUATELY CONTROLLED WITH A SOMATOSTATIN ANALOG (SSA) (SUCH AS OCTREOTIDE) FOR AT LEAST 3 MONTHS, AND (3) USED IN COMBINATION WITH SSA THERAPY. RENEWAL CRITERIA: POSITIVE RESPONSE TO THERAPY (SUCH AS REDUCTION IN THE NUMBER OF DAILY STOOLS).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST, ENDOCRINOLOGIST, OR A GASTROENTEROLOGIST.

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

OTHER CRITERIA
N/A

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 SIDE EFFECTS HAVE LIMITED THE DOSE OF LACTULOSE, OR (2) DIAGNOSIS OF TRAVELERS' DIARRHEA CAUSED BY NONINVASIVE STRAINS OF ESCHERICHIA COLI AND (A)TRIAL AND FAILURE OF OR CONTRAINDICATIONS TO ONE OF THE FOLLOWING: CIPROFLOXACIN, LEVOFLOXACIN, OFLOXACIN, OR AZITHROMYCIN, OR (B) RESISTANCE TO ALL OF THE FOLLOWING: CIPROFLOXACIN, LEVOFLOXACIN, OFLOXACIN, OR AZITHROMYCIN, OR (3) DIAGNOSIS OF MODERATE TO SEVERE IRRITABLE BOWEL DISEASE, INCLUDING BLOATING, WITHOUT CONSTIPATION AND WITH (A) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO FIRST LINE THERAPY INCLUDING AN ANTISPASMODIC AGENT SUCH AS DICYCLOMINE AND AN ANTIDIARRHEAL AGENT SUCH AS LOPERAMIDE OR DIPHENOXYLATE/ATROPINE. RENEWAL CRITERIA: FOR HEPATIC ENCEPHALOPATHY, PATIENT HAS BEEN SEEN BY THE PRESCRIBER IN THE PAST 14 MONTHS AND POSITIVE RESPONSE TO THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST 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 MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE 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, OR (C) 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 LASTING 3 OR MORE DAYS WITHIN THE LAST 12 MONTHS, OR (B) AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT IN THE LAST 12 MONTHS. FOR CHRONIC URTICARIA: MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO A MAXIMALLY TOLERATED DOSE OF AN H1 ANTIHISTAMINE SUCH AS LEVOCETIRIZINE AND PATIENT STILL EXPERIENCES HIVES ON MOST DAYS OF THE WEEK. 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, POSITIVE RESPONSE TO THERAPY. (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

XTANDI

MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NON-METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (NMCSPC): HIGH RISK FOR METASTASIS (I.E. PSA DOUBLED OVER 9 MONTHS OR LESS). METASTATIC CRPC (MCRPC), NMCRPC, METASTATIC CSPC (MCSPC), NMCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: MCRPC, NMCRPC, MCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG.

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

ZURZUVAE

MEDICATION(S)
ZURZUVAE

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 POSTPARTUM DEPRESSION, (A) AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE OTHER ANTIDEPRESSANT THERAPY [SUCH AS AN SSRI, SNRI, OR TRICYCLIC ANTIDEPRESSANT (TCA)], AND (B) ONSET OF SYMPTOMS ARE IN THE THIRD TRIMESTER OR WITHIN FOUR WEEKS OF DELIVERY, AND (C) PRESCRIBER ATTESTS THE PATIENT HAS BEEN COUNSELED AND HAS AGREED TO FOLLOW INSTRUCTIONS TO NOT DRIVE OR OPERATE MACHINERY UNTIL AT LEAST 12 HOURS AFTER TAKING EACH DOSE OF ZURZUVAE FOR THE DURATION OF THE 14-DAY TREATMENT COURSE AND THAT PATIENTS ARE INFORMED THEY MAY NOT BE ABLE TO ASSESS THEIR OWN DRIVING COMPETENCE OR THE DEGREE OF DRIVING IMPAIRMENT CAUSED BY ZURZUVAE.

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