ABATACEPT IV

Products Affected

• ORENCIA (WITH MALTOSE)

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. |
| Coverage Duration | RA, PJIA, PSA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. AGVHD: 12 MONTHS. |
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

ABATACEPT SQ

Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

ABEMACICLIB

Products Affected

VERZENIO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ABIRATERONE

Products Affected

• abiraterone

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC), METASTATIC CASTRATION- RESISTANT PROSTATE CANCER (MCRPC): 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 |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ABIRATERONE SUBMICRONIZED

Products Affected

YONSA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ACALABRUTINIB

Products Affected

• CALQUENCE (ACALABRUTINIB MAL)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT BRUKINSA, WHERE INDICATIONS ALIGN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ADAGRASIB

Products Affected

KRAZATI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ADALIMUMAB

Products Affected

- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML
- HUMIRA(CF)

- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OPTHALMOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE- MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PJIA, PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIEN E, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, PJIA, PSA, AS, PSO, HIDRADENITIS SUPPURATIVA, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AFATINIB

Products Affected

• GILOTRIF

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS. |
| Other Criteria | METASTATIC NSCLC WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AGALSIDASE BETA

Products Affected

FABRAZYME

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | FABRY DISEASE: INITIAL: 1) SYMPTOMATIC OR EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS, AND 2) ONE OF THE FOLLOWING: (A) FEMALES: GALACTOSIDASE ALPHA (GLA) GENE MUTATION VIA GENETIC TESTING, OR (B) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

ALECTINIB

Products Affected

ALECENSA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ALPELISIB

Products Affected

 PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AMBRISENTAN

Products Affected

• ambrisentan

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: INITIAL: DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AMIVANTAMAB-VMJW

Products Affected

RYBREVANT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ANAKINRA

Products Affected

KINERET

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. ALL OTHERS: 12 MONTHS. |
| Other Criteria | RA: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

APALUTAMIDE

Products Affected

• ERLEADA ORAL TABLET 240 MG, 60 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

APOMORPHINE

Products Affected

• apomorphine

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | PD: INITIAL: PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PD. RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WHILE ON THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

APOMORPHINE - SL

Products Affected

 KYNMOBI SUBLINGUAL FILM 10 MG, 10-15-20-25-30 MG, 15 MG, 20 MG, 25 MG, 30 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | PARKINSONS DISEASE (PD): INITIAL: 18 YEARS OF AGE OR OLDER. |
| Prescriber Restrictions | PD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | PD: INITIAL: PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

APREMILAST

Products Affected

- OTEZLA
- OTEZLA STARTER

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: MILD PLAQUE PSORIASIS (PSO): ONE OF THE FOLLOWING: 1) PSORIASIS COVERING 2 PERCENT OF BODY SURFACE AREA (BSA), 2) STATIC PHYSICIAN GLOBAL ASSESSMENT (SPGA) SCORE OF 2, OR 3) PSORIASIS AREA AND SEVERITY INDEX (PASI) SCORE OF 2 TO 9. MODERATE TO SEVERE PSO: 1) PSORIASIS COVERING 3 PERCENT OR MORE OF BSA, OR 2) PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. BEHCETS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. MILD PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL SYSTEMIC AGENT (E.G., METHOTREXATE, ACITRETIN, CYCLOSPORINE) AND ONE CONVENTIONAL TOPICAL AGENT (E.G., PUVA, UVB, TOPICAL CORTICOSTEROIDS). MODERATE TO SEVERE PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. BEHCETS DISEASE: 1) HAS ORAL ULCERS OR A HISTORY OF RECURRENT ORAL ULCERS BASED ON CLINICAL SYMPTOMS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OR MORE CONSERVATIVE TREATMENTS (E.G., COLCHICINE, TOPICAL CORTICOSTEROID, ORAL CORTICOSTEROID). RENEWAL: PSA, PSO, BEHCETS DISEASE: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ASCIMINIB

Products Affected

SCEMBLIX ORAL TABLET 20 MG, 40 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND SCEMBLIX IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ASFOTASE

Products Affected

• STRENSIQ

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HYPOPHOSPHATASIA (HPP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, OR METABOLIC SPECIALIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|----------------|--|
| Other Criteria | INITIAL: PERINATAL/INFANTILE-ONSET HPP: 1) 6 |
| | MONTHS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) |
| | POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE |
| | PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS |
| | CONFIRMED BY GENETIC TESTING OR TWO OF THE |
| | FOLLOWING: (A) SERUM ALKALINE PHOSPHATASE (ALP) |
| | LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT |
| | AGE, (B) ELEVATED SERUM PYRIDOXAL-5'-PHOSPHATE |
| | (PLP) LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN |
| | THE PREVIOUS WEEK, (C) URINE |
| | PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF |
| | NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC |
| | EVIDENCE OF HPP, (E) AT LEAST TWO OF THE |
| | FOLLOWING: (I) RACHITIC CHEST DEFORMITY, (II) |
| | CRANIOSYNOSTOSIS, (III) DELAY IN SKELETAL GROWTH |
| | RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) |
| | HISTORY OF VITAMIN B6 DEPENDENT SEIZURES, (V) |
| | NEPHROCALCINOSIS OR HISTORY OF ELEVATED SERUM |
| | CALCIUM, (VI) HISTORY OR PRESENCE OF NON- |
| | TRAUMATIC POSTNATAL FRACTURE AND DELAYED |
| | FRACTURE HEALING. JUVENILE-ONSET HPP: 1) 18 YEARS |
| | OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE |
| | FOR A TNSALP ALPL GENE MUTATION AS CONFIRMED |
| | BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) |
| | SERUM ALP LEVEL BELOW THAT OF NORMAL RANGE |
| | FOR PATIENT AGE, (B) ELEVATED SERUM PLP LEVELS |
| | AND NO VITAMIN B6 SUPPLEMENTATION IN THE |
| | PREVIOUS WEEK, (C) URINE PEA LEVEL ABOVE THAT OF |
| | NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC |
| | EVIDENCE OF HPP, (E) AT LEAST TWO OF THE |
| | FOLLOWING: (I) RACHITIC DEFORMITIES, (II) |
| | PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 |
| | YEARS OF AGE, (III) DELAY IN SKELETAL GROWTH |
| | RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) |

| PA Criteria | Criteria Details |
|------------------------|---|
| | HISTORY OR PRESENCE OF NON-TRAUMATIC FRACTURES OR DELAYED FRACTURE HEALING. ALL INDICATIONS: 1) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE, 2) CALCIUM OR PHOSPHATE LEVELS ARE NOT BELOW THE NORMAL RANGE, 3) NOT HAVE A TREATABLE FORM OF RICKETS. RENEWAL: ALL INDICATIONS: 1) IMPROVEMENT IN THE SKELETAL CHARACTERISTICS OF HPP, AND 2) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ATEZOLIZUMAB

Products Affected

• TECENTRIQ

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ATOGEPANT

Products Affected

• QULIPTA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | MIGRAINE PREVENTION: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: 1) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY, AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AVAPRITINIB

Products Affected

AYVAKIT

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AVATROMBOPAG

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: CHRONIC LIVER DISEASE (CLD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, ENDOCRINOLOGIST, OR A SURGEON. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| Coverage Duration | CLD: 1 MONTH. CHRONIC ITP: INITIAL: 2 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: CLD: 1) PLANNED PROCEDURE 10 TO 13 DAYS AFTER INITIATION OF DOPTELET, AND 2) NOT RECEIVING OTHER THROMBOPOIETIN RECEPTOR AGONISTS (E.G., ROMIPLOSTIM, ELTROMBOPAG, ETC.). CHRONIC ITP: TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS OR IMMUNOGLOBULINS OR INSUFFICIENT RESPONSE TO SPLENECTOMY. RENEWAL: CHRONIC ITP: PATIENT HAD A CLINICAL RESPONSE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AXITINIB

Products Affected

• INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AZACITIDINE

Products Affected

ONUREG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AZTREONAM

Products Affected

CAYSTON

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | 7 YEARS OF AGE OR OLDER |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BARICITINIB

Products Affected

OLUMIANT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SEVERE ALOPECIA AREATA: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. |
| Coverage Duration | RA, SEVERE ALOPECIA AREATA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ. SEVERE ALOPECIA AREATA: 1) AT LEAST 50 PERCENT SCALP HAIR LOSS AS MEASURED BY THE SEVERITY OF ALOPECIA TOOL (SALT) FOR MORE THAN 6 MONTHS, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR SEVERE ALOPECIA AREATA OR OTHER JAK INHIBITORS FOR ANY INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR SEVERE ALOPECIA AREATA OR OTHER JAK INHIBITORS FOR ANY INDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

BECAPLERMIN

Products Affected

REGRANEX

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | DIABETIC NEUROPATHIC ULCERS: PRESCRIBED BY OR IN CONSULTATION WITH A VASCULAR SURGEON, PODIATRIST, ENDOCRINOLOGIST, PHYSICIAN PRACTICING IN A SPECIALTY WOUND CLINIC OR INFECTIOUS DISEASE SPECIALIST. |
| Coverage Duration | 3 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEDAQUILINE

Products Affected

· SIRTURO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 24 WEEKS |
| Other Criteria | PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB): SIRTURO USED IN COMBINATION WITH AT LEAST 3 OTHER ANTIBIOTICS FOR THE TREATMENT OF PULMONARY MDR-TB. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BELIMUMAB

- BENLYSTA INTRAVENOUS
- BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. LUPUS NEPHRITIS (LN): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL: SLE: CURRENTLY TAKING CORTICOSTEROIDS, ANTIMALARIALS, NSAIDS, OR IMMUNOSUPPRESSIVE AGENTS. RENEWAL: SLE: PATIENT HAD CLINICAL IMPROVEMENT. LN: IMPROVEMENT IN RENAL RESPONSE FROM BASELINE LABORATORY VALUES (I.E., EGFR OR PROTEINURIA) AND/OR CLINICAL PARAMETERS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BELUMOSUDIL

Products Affected

REZUROCK

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BELZUTIFAN

Products Affected

• WELIREG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BENDAMUSTINE

- bendamustine intravenous recon soln
- BENDAMUSTINE INTRAVENOUS SOLUTION
- BENDEKA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BENRALIZUMAB

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | ASTHMA: INITIAL: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| Coverage Duration | INITIAL: 4 MONTHS, RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|----------------------------|---|
| PA Criteria Other Criteria | ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NO CONCURRENT USE WITH XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. RENEWAL: 1) NO CONCURRENT USE WITH XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEVI FROM PRETREATMENT |
| | BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BETAINE

Products Affected

• betaine

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEVACIZUMAB-ADCD

Products Affected

VEGZELMA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEVACIZUMAB-AWWB

Products Affected

MVASI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEVACIZUMAB-BVZR

Products Affected

ZIRABEV

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEXAROTENE

Products Affected

• bexarotene

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BINIMETINIB

Products Affected

MEKTOVI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BORTEZOMIB

- bortezomib injection recon soln 1 mg, 2.5 VELCADE mg
- BORTEZOMIB INTRAVENOUS RECON SOLN

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BOSENTAN

- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: INITIAL: 1) 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, AND 2) NOT CONCURRENTLY TAKING CYCLOSPORINE A OR GLYBURIDE. RENEWAL: 1) NOT CONCURRENTLY TAKING CYCLOSPORINE A OR GLYBURIDE, AND 2) AGES 3 TO 17 YEARS: (A) IMPROVEMENT IN PVR, OR (B) HAS REMAINED STABLE OR SHOWN IMPROVEMENT IN EXERCISE ABILITY. AGES 18 YEARS AND OLDER: (A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR (B) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BOSUTINIB

Products Affected

• BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PREVIOUSLY TREATED (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND BOSULIF IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BRIGATINIB

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

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

C1 ESTERASE INHIBITOR-CINRYZE

Products Affected

CINRYZE

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

C1 ESTERASE INHIBITOR-HAEGARDA

Products Affected

• HAEGARDA SUBCUTANEOUS RECON SOLN 2,000 UNIT, 3,000 UNIT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST. |
| Coverage Duration | INITIAL AND RENEWAL: 12 MONTHS. |
| Other Criteria | HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CABOZANTINIB

Products Affected

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

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CABOZANTINIB S-MALATE - CABOMETYX

Products Affected

 CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CANAKINUMAB

Products Affected

• ILARIS (PF)

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA), ADULT-ONSET STILLS DISEASE (AOSD): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: AOSD/SJIA: 6 MOS, CAPS: LIFETIME, ALL OTHER DIAGNOSES: 12 MOS. RENEWAL: AOSD/SJIA: 12 MOS. |
| Other Criteria | INITIAL: CAPS: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. AOSD, SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUGS). RENEWAL: AOSD, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

CANNABIDIOL

Products Affected

• EPIDIOLEX

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | DRAVET SYNDROME (DS), LENNOX-GASTAUT SYNDROME (LGS), TUBEROUS SCLEROSIS COMPLEX (TSC): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 12 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: LENNOX-GASTAUT SYNDROME (LGS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING ANTIEPILEPTIC MEDICATIONS: RUFINAMIDE, FELBAMATE, CLOBAZAM, TOPIRAMATE, LAMOTRIGINE, CLONAZEPAM. RENEWAL: DS, LGS, TSC: CONFIRMATION OF DIAGNOSIS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAPLACIZUMAB YHDP

Products Affected

CABLIVI INJECTION KIT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | ACQUIRED THROMBOTIC THROMBOCYTOPENIA PURPURA (ATTP): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ATTP: CABLIVI WAS PREVIOUSLY INITIATED AS PART OF THE FDA APPROVED TREATMENT REGIMEN IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY WITHIN AN INPATIENT SETTING. THE PATIENT HAS NOT EXPERIENCED MORE THAN TWO RECURRENCES OF ATTP WHILE ON CABLIVI THERAPY (I.E., NEW DROP IN PLATELET COUNT REQUIRING REPEAT PLASMA EXCHANGE DURING 30 DAYS POST-PLASMA EXCHANGE THERAPY [PEX] AND UP TO 28 DAYS OF EXTENDED THERAPY). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAPMATINIB

Products Affected

TABRECTA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CARGLUMIC ACID

Products Affected

• carglumic acid

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ACUTE OR CHRONIC HYPERAMMONEMIA (HA) DUE TO N ACETYLGLUTAMATE SYNTHASE (NAGS) DEFICIENCY: NAGS GENE MUTATION IS CONFIRMED BY BIOCHEMICAL OR GENETIC TESTING. ACUTE HA DUE TO PROPIONIC ACIDEMIA (PA): 1) CONFIRMED BY ELEVATED METHYLCITRIC ACID AND NORMAL METHYLMALONIC ACID, OR 2) GENETIC TESTING CONFIRMS MUTATION IN THE PCCA OR PCCB GENE. ACUTE HA DUE TO METHYLMALONIC ACIDEMIA (MMA): 1) CONFIRMED BY ELEVATED METHYLMALONIC ACID, METHYLCITRIC ACID, OR 2) GENETIC TESTING CONFIRMS MUTATION IN THE MMUT, MMA, MMAB OR MMADHC GENES. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | ACUTE HA DUE TO NAGS/PA/MMA: 7 DAYS. CHRONIC HA DUE TO NAGS: INITIAL: 6 MOS, RENEWAL: 12 MOS. |
| Other Criteria | RENEWAL: CHRONIC HA DUE TO NAGS: PATIENT HAS SHOWN CLINICAL IMPROVEMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CERITINIB

Products Affected

ZYKADIA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CETUXIMAB

Products Affected

• ERBITUX

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CLADRIBINE

- MAVENCLAD (10 TABLET PACK)
- MAVENCLAD (4 TABLET PACK)
- MAVENCLAD (5 TABLET PACK)
- MAVENCLAD (6 TABLET PACK)
- MAVENCLAD (7 TABLET PACK)
- MAVENCLAD (8 TABLET PACK)
- MAVENCLAD (9 TABLET PACK)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 48 WEEKS. |
| Other Criteria | RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): INITIAL: HAS NOT RECEIVED A TOTAL OF TWO YEARS OF MAVENCLAD TREATMENT (I.E., TWO YEARLY TREATMENT COURSES OF TWO CYCLES IN EACH). RENEWAL: 1) HAS DEMONSTRATED CLINICAL BENEFIT COMPARED TO PRE-TREATMENT BASELINE, 2) DOES NOT HAVE LYMPHOPENIA, AND 3) HAS NOT RECEIVED A TOTAL OF TWO YEARS OF MAVENCLAD TREATMENT (I.E., TWO YEARLY TREATMENT COURSES OF TWO CYCLES IN EACH). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CLOBAZAM-SYMPAZAN

Products Affected

SYMPAZAN

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | LENNOX-GASTAUT SYNDROME (LGS): THERAPY IS PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | LGS: 1) UNABLE TO TAKE TABLETS OR SUSPENSIONS, AND 2) TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF CLOBAZAM. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COBIMETINIB

Products Affected

· COTELLIC

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COLCHICINE

Products Affected

• colchicine oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | PROPHYLAXIS OF GOUT FLARES: 16 YEARS AND OLDER |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PROPHYLAXIS OF GOUT FLARES: TRIAL OF OR CONTRAINDICATION TO COLCHICINE CAPSULES (MITIGARE) IF AGE 18 YEARS OR OLDER. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CORTICOTROPIN

Products Affected

- ACTHAR
- · CORTROPHIN GEL

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | INITIAL: NOT APPROVED FOR DIAGNOSTIC PURPOSES. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MULTIPLE SCLEROSIS (MS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST/IMMUNOLOGIST, OPHTHALMOLOGIST, PULMONOLOGIST OR NEPHROLOGIST. |
| Coverage Duration | INFANTILE SPASMS AND MS: 28 DAYS. OTHER FDA APPROVED INDICATIONS: INITIAL AND RENEWAL: 28 DAYS |
| Other Criteria | INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS: TRIAL OF OR CONTRAINDICATION TO INTRAVENOUS (IV) CORTICOSTEROIDS. ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: TRIAL OF OR CONTRAINDICATION TO A STANDARD OF CARE THERAPY. RENEWAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: 1) DEMONSTRATED CLINICAL BENEFIT WHILE ON THERAPY AS INDICATED BY SYMPTOM RESOLUTION AND/OR NORMALIZATION OF LABORATORY TESTS, AND 2) CONTINUES TO POSSESS CONTRAINDICATION TO IV CORTICOSTEROIDS. PART B BEFORE PART D STEP THERAPY, APPLIES ONLY TO BENEFICIARIES IN AN MAPD PLAN. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

CRIZANLIZUMAB-TMCA

Products Affected

ADAKVEO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | SICKLE CELL DISEASE (SCD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST |
| Coverage Duration | INITIAL: 12 MONTHS. RENEWAL: LIFETIME |
| Other Criteria | SCD: INITIAL: AGES 18 YEARS OR OLDER: 1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, 2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR 3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME. AGES 16 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: MAINTAINED OR EXPERIENCED A REDUCTION IN ACUTE COMPLICATIONS OF SCD. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CRIZOTINIB

Products Affected

XALKORI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CYSTEAMINE HYDROCHLORIDE

Products Affected

- CYSTADROPS
- · CYSTARAN

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DABRAFENIB

Products Affected

• TAFINLAR ORAL CAPSULE

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DABRAFENIB SUSPENSION

Products Affected

 TAFINLAR ORAL TABLET FOR SUSPENSION

| PA Criteria | Criteria Details |
|---------------------------------|---------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNABLE TO SWALLOW TAFINILAR CAPSULES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DACOMITINIB

Products Affected

VIZIMPRO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC): NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DALFAMPRIDINE

Products Affected

• dalfampridine

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | MULTIPLE SCLEROSIS (MS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | MS: INITIAL: HAS SYMPTOMS OF A WALKING DISABILITY SUCH AS MILD TO MODERATE BILATERAL LOWER EXTREMITY WEAKNESS OR UNILATERAL WEAKNESS PLUS LOWER EXTREMITY OR TRUNCAL ATAXIA. RENEWAL: IMPROVEMENT IN WALKING ABILITY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DARATUMUMAB

Products Affected

DARZALEX

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DARATUMUMAB-HYALURONIDASE-FIHJ

Products Affected

DARZALEX FASPRO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DAROLUTAMIDE

Products Affected

• NUBEQA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DASATINIB

Products Affected

 SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PREVIOUSLY-TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND SPRYCEL IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DECITABINE/CEDAZURIDINE

Products Affected

· INQOVI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DEFERASIROX

Products Affected

• deferasirox

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 1000 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). NON-TRANSFUSION DEPENDENT THALASSEMIA (NTDT): 1) SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 300 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS) AND 2) LIVER IRON CONCENTRATION (LIC) OF 5 MG FE/G DRY WEIGHT OR GREATER. RENEWAL: CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). NTDT: 1) SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 300 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS) OR 2) LIC OF 3 MG FE/G DRY WEIGHT OR GREATER. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: CHRONIC IRON OVERLOAD: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL FOR ALL INDICATIONS: FORMULARY VERSION OF DEFERASIROX SPRINKLE: TRIAL OF OR CONTRAINDICATION TO GENERIC DEFERASIROX TABLET OR TABLET FOR ORAL SUSPENSION. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

DEFERIPRONE

Products Affected

- deferiprone FERRIPROX (2 TIMES A DAY)
- FERRIPROX ORAL SOLUTION

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | TRANSFUSIONAL IRON OVERLOAD: RENEWAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). |
| Age Restrictions | |
| Prescriber Restrictions | TRANSFUSIONAL IRON OVERLOAD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL: TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES: 1) TRIAL OF, CONTRAINDICATION, INTOLERABLE TOXICITIES, OR CLINICALLY SIGNIFICANT ADVERSE EFFECTS TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE, OR 2) CURRENT CHELATION THERAPY (I.E., FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE) IS INADEQUATE. TRANSFUSIONAL IRON OVERLOAD DUE TO SICKLE CELL DISEASE OR OTHER ANEMIAS: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

DEFEROXAMINE

Products Affected

• deferoxamine

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CHRONIC IRON OVERLOAD: INITIAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 1000 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). RENEWAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). |
| Age Restrictions | CHRONIC IRON OVERLOAD: INITIAL: 3 YEARS OR OLDER |
| Prescriber Restrictions | CHRONIC IRON OVERLOAD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DENOSUMAB-XGEVA

Products Affected

• XGEVA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DEUTETRABENAZINE

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG,
- 24 MG, 6 MG
- AUSTEDO XR TITRATION KT(WK1-4)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HUNTINGTON DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST. TARDIVE DYSKINESIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TARDIVE DYSKINESIA: HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DICLOFENAC GEL

Products Affected

• diclofenac sodium topical gel 3 %

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DICLOFENAC TOPICAL SOLUTION

Products Affected

• diclofenac sodium topical solution in metered-dose pump

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | OSTEOARTHRITIS OF THE KNEE: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DICLOFENAC SODIUM 1% TOPICAL GEL AND A FORMULARY VERSION OF DICLOFENAC SODIUM 1.5% TOPICAL DROPS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DIMETHYL FUMARATE

Products Affected

• dimethyl fumarate oral capsule,delayed release(drlec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DIROXIMEL FUMARATE

Products Affected

VUMERITY

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DOSTARLIMAB-GXLY

Products Affected

• JEMPERLI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DRONABINOL

Products Affected

• dronabinol

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY: TRIAL OF OR CONTRAINDICATION TO ONE ANTIEMETIC THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D FOR THE INDICATION OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DROXIDOPA

Products Affected

• droxidopa

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH): INITIAL: 1) BASELINE BLOOD PRESSURE READINGS WHILE THE PATIENT IS SITTING AND ALSO WITHIN 3 MINUTES OF STANDING FROM A SUPINE POSITION. 2) A DECREASE OF AT LEAST 20 MMHG IN SYSTOLIC BLOOD PRESSURE OR 10 MMHG DIASTOLIC BLOOD PRESSURE WITHIN THREE MINUTES AFTER STANDING FROM A SITTING POSITION. |
| Age Restrictions | |
| Prescriber Restrictions | NOH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR CARDIOLOGIST. |
| Coverage Duration | INITIAL: 3 MONTHS RENEWAL: 12 MONTHS |
| Other Criteria | NOH: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DUPILUMAB

Products Affected

- DUPIXENT PEN
- DUPIXENT SYRINGE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: EOSINOPHILIC ASTHMA: BLOOD EOSINOPHIL LEVEL OF 150 TO 1500 CELLS/MCL WITHIN THE PAST 12 MONTHS. EOSINOPHILIC ESOPHAGITIS (EOE): DIAGNOSIS CONFIRMED BY ESOPHAGOGASTRODUODENOSCOPY (EGD) WITH BIOPSY. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: AD, PN: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. CRSWNP: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. EOE: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, ALLERGIST, OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: AD, CRSWNP, EOE, PN: 6 MOS, ASTHMA: 4 MOS. RENEWAL: ALL INDICATIONS: 12 MOS. |

| PA Criteria | Criteria Details |
|----------------|--|
| Other Criteria | INITIAL: AD: 1) AD COVERING AT LEAST 10 PERCENT OF |
| | BODY SURFACE AREA OR AD AFFECTING THE FACE, |
| | HEAD, NECK, HANDS, FEET, GROIN, OR INTERTRIGINOUS |
| | AREAS, 2) INTRACTABLE PRURITUS OR |
| | CRACKING/OOZING/BLEEDING OF AFFECTED SKIN, 3) |
| | TRIAL OF OR CONTRAINDICATION TO ONE TOPICAL |
| | (CORTICOSTEROID, CALCINEURIN INHIBITOR, PDE4 |
| | INHIBITOR, OR JAK INHIBITOR), AND 4) NO |
| | CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS |
| | OR JAK INHIBITORS FOR AD. ASTHMA: 1) CONCURRENT |
| | THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY- |
| | TOLERATED DOSE OF AN INHALED CORTICOSTEROID |
| | (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) |
| | ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC |
| | CORTICOSTEROID BURST LASTING 3 OR MORE DAYS |
| | WITHIN THE PAST 12 MONTHS, OR ONE SERIOUS |
| | EXACERBATION REQUIRING HOSPITALIZATION OR ER |
| | VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM |
| | CONTROL DESPITE CURRENT THERAPY AS EVIDENCED |
| | BY AT LEAST THREE OF THE FOLLOWING WITHIN THE |
| | PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE |
| | THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO |
| | ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN |
| | TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO |
| | ASTHMA, AND 3) NO CONCURRENT USE WITH XOLAIR OR |
| | OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. |
| | CRSWNP: 1) EVIDENCE OF NASAL POLYPS BY DIRECT |
| | EXAMINATION, ENDOSCOPY OR SINUS CT SCAN, 2) |
| | INADEQUATELY CONTROLLED DISEASE AS |
| | DETERMINED BY USE OF SYSTEMIC STEROIDS IN THE |
| | PAST 2 YEARS OR ENDOSCOPIC SINUS SURGERY, AND 3) A |
| | 90 DAY TRIAL OF ONE TOPICAL NASAL |
| | CORTICOSTEROID. PN: 1) CHRONIC PRURITIS (ITCH MORE |
| | THAN 6 WEEKS), MULTIPLE PRURIGINOUS LESIONS, AND |

| PA Criteria | Criteria Details |
|------------------------|--|
| | HISTORY OR SIGN OF A PROLONGED SCRATCHING BEHAVIOR, 2) TRIAL OF OR CONTRAINDICATION TO ONE TOPICAL (CORTICOSTEROID OR CALCIPOTRIOL). RENEWAL: AD: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS OR JAK INHIBITORS FOR AD. CRSWNP, EOE: IMPROVEMENT WHILE ON THERAPY. ASTHMA: 1) NO CONCURRENT USE WITH XOLAIR, OR OTHER ANTI-IL5 BIOLOGICS FOR ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. PN: IMPROVEMENT OR REDUCTION OF PRURITIS OR PRURIGINOUS LESIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DUVELISIB

Products Affected

COPIKTRA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EDARAVONE

Products Affected

· RADICAVA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR ALS SPECIALIST AT AN ALS SPECIALTY CENTER OR CARE CLINIC. |
| Coverage Duration | ALS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | ALS: INITIAL: 1) DURATION OF DISEASE (FROM ONSET OF SYMPTOMS) IS LESS THAN OR EQUAL TO 2 YEARS, 2) NORMAL RESPIRATORY FUNCTION, 3) HAS MILD TO MODERATE ALS WITH A SCORE OF 2 OR HIGHER IN ALL OF THE FOLLOWING 12 ITEMS OF THE AMYOTROPHIC LATERAL SCLEROSIS FUNCTIONAL RATING SCALE REVISED (ALSFRS-R): SPEECH, SALIVATION, SWALLOWING, HANDWRITING, CUTTING FOOD, DRESSING AND HYGIENE, TURNING IN BED, WALKING, CLIMBING STAIRS, DYSPNEA, ORTHOPNEA, RESPIRATORY INSUFFICIENCY, AND 4) TRIAL OF RILUZOLE TABLET OR CURRENTLY TAKING RILUZOLE TABLET. RENEWAL: 1) DOES NOT REQUIRE INVASIVE VENTILATION, AND 2) HAS IMPROVED BASELINE FUNCTIONAL ABILITY OR HAS MAINTAINED A SCORE OF 2 OR HIGHER IN ALL 12 ITEMS OF THE ALSFRS-R. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

EFLAPEGRASTIM-XNST

Products Affected

ROLVEDON

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NYVEPRIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELACESTRANT

Products Affected

• ORSERDU ORAL TABLET 345 MG, 86 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELAGOLIX SODIUM

Products Affected

 ORILISSA ORAL TABLET 150 MG, 200 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: DIAGNOSIS IS CONFIRMED VIA SURGICAL OR DIRECT VISUALIZATION (E.G., PELVIC ULTRASOUND) OR HISTOPATHOLOGICAL CONFIRMATION (E.G., LAPAROSCOPY OR LAPAROTOMY) IN THE LAST 10 YEARS. |
| Age Restrictions | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: 18 YEARS OF AGE OR OLDER. |
| Prescriber Restrictions | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS |
| Other Criteria | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 2) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND A PROGESTIN-CONTAINING PREPARATION. RENEWAL: 1) IMPROVEMENT IN PAIN ASSOCIATED WITH ENDOMETRIOSIS WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

ELAPEGADEMASE-LVLR

Products Affected

REVCOVI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | ADENOSINE DEAMINASE SEVERE COMBINED IMMUNE DEFICIENCY (ADA-SCID): INITIAL: ADA-SCID AS MANIFESTED BY: 1) CONFIRMATORY GENETIC TEST, OR 2) SUGGESTIVE LABORATORY FINDINGS (E.G., ELEVATED DEOXYADENOSINE NUCLEOTIDE [DAXP] LEVELS, LYMPHOPENIA) AND HALLMARK SIGNS/SYMPTOMS (E.G., RECURRENT INFECTIONS, FAILURE TO THRIVE, PERSISTENT DIARRHEA). |
| Age Restrictions | |
| Prescriber Restrictions | ADA-SCID: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH IMMUNOLOGIST, HEMATOLOGIST/ONCOLOGIST, OR PHYSICIAN SPECIALIZING IN INHERITED METABOLIC DISORDERS. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | ADA-SCID: RENEWAL: 1) IMPROVEMENT OR MAINTENANCE OF IMMUNE FUNCTION FROM BASELINE, AND 2) HAS NOT RECEIVED SUCCESSFUL HCT OR GENE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

Products Affected

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: LIFETIME. |
| Other Criteria | CF: RENEWAL: 1) MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR 2) REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELIGLUSTAT

Products Affected

· CERDELGA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELOSULFASE ALFA

Products Affected

VIMIZIM

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELRANATAMAB-BCMM

Products Affected

- ELREXFIO 44 MG/1.1 ML VIAL
- ELREXFIO SUBCUTANEOUS SOLUTION 40 MG/ML

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | RELAPSED OR REFRACTORY MULTIPLE MYELOMA: RENEWAL: 1) HAS RECEIVED AT LEAST 24 WEEKS OF TREATMENT WITH ELREXFIO, AND 2) HAS RESPONDED TO TREATMENT (PARTIAL RESPONSE OR BETTER), AND HAS MAINTAINED THIS RESPONSE FOR AT LEAST 2 MONTHS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELTROMBOPAG

Products Affected

- PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| Coverage Duration | ITP: INITIAL: 2 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO. |
| Other Criteria | INITIAL: PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA PURPURA (ITP): TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. ALL INDICATIONS: APPROVAL FOR PROMACTA ORAL SUSPENSION PACKETS REQUIRES A TRIAL OF PROMACTA TABLETS OR PATIENT IS UNABLE TO TAKE TABLET FORMULATION. RENEWAL: ITP: PATIENT HAS SHOWN A CLINICAL RESPONSE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EMAPALUMAB-LZSG

Products Affected

GAMIFANT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH): INITIAL: 1) A GENETIC TEST IDENTIFYING HLH-ASSOCIATED GENE MUTATION (E.G., PRF1, UNC13D), OR 2) HAS AT LEAST FIVE OF THE FOLLOWING EIGHT DIAGNOSTIC CRITERIA FOR HLH: (A) FEVER, (B) SPLENOMEGALY, (C) CYTOPENIAS (AFFECTING AT LEAST 2 OF 3 CELL LINEAGES), (D) HYPERTRIGLYCERIDEMIA OR HYPOFIBRINOGENEMIA, (E) HEMOPHAGOCYTOSIS IN BONE MARROW OR SPLEEN OR LYMPH NODES AND NO EVIDENCE OF MALIGNANCY, (F) LOW OR ABSENT NATURAL KILLER-CELL ACTIVITY, (G) FERRITIN LEVEL OF 500 MCG/L OR GREATER, (H) SOLUBLE CD25 LEVEL OF 2,400 U/ML OR GREATER. |
| Age Restrictions | |
| Prescriber Restrictions | HLH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN IMMUNOLOGIST, HEMATOLOGIST, OR ONCOLOGIST. |
| Coverage Duration | INITIAL AND RENEWAL: 8 WEEKS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | HLH: INITIAL: 1) CONCURRENT THERAPY WITH DEXAMETHASONE, AND 2) ONE OF THE FOLLOWING: (A) HAS REFRACTORY, RECURRENT, OR PROGRESSIVE DISEASE, OR (B) HAD A TRIAL OF OR INTOLERANCE TO CONVENTIONAL HLH THERAPY (I.E., CHEMOTHERAPY, STEROIDS, IMMUNOTHERAPY). RENEWAL: 1) HAS NOT RECEIVED SUCCESSFUL HEMATOPOIETIC STEM CELL TRANSPLANTATION, AND 2) DEMONSTRATED IMPROVED IMMUNE SYSTEM RESPONSE FROM BASELINE (E.G., RESOLUTION OF FEVER, DECREASED SPLENOMEGALY, IMPROVEMENT IN CNS SYMPTOMS, IMPROVED CBC, INCREASED FIBRINOGEN LEVELS, REDUCED D-DIMER, REDUCED FERRITIN, REDUCED SOLUBLE CD25 LEVELS.) |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENASIDENIB

Products Affected

• IDHIFA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENCORAFENIB

Products Affected

• BRAFTOVI ORAL CAPSULE 75 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENTRECTINIB

Products Affected

 ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENZALUTAMIDE

Products Affected

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

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | INITIAL: CASTRATION-RESISTANT PROSTATE CANCER (CRPC) THAT IS NOT METASTATIC: HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). CRPC (INCLUDES NON-METASTATIC AND METASTATIC), 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: CRPC (INCLUDES NON-METASTATIC AND METASTATIC), 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EPCORITAMAB-BYSP

Products Affected

EPKINLY

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EPOETIN ALFA-EPBX

Products Affected

 RETACRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL OF LESS THAN 10G/DL. ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL LESS THAN 13G/DL. RENEWAL: 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. 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. ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. 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 Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE: INITIAL/RENEWAL: 12 MONTHS. SURGERY: 1 MONTH. |

| PA Criteria | Criteria Details |
|------------------------|--|
| Other Criteria | RENEWAL: CKD: NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EPOPROSTENOL IV

Products Affected

• epoprostenol

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL AND RENEWAL: 12 MONTHS |
| Other Criteria | PAH: RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS IMPROVED OR REMAINED STABLE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ERDAFITINIB

Products Affected

 BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ERLOTINIB

Products Affected

• erlotinib oral tablet 100 mg, 150 mg, 25 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC NSCLC WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ESKETAMINE

Products Affected

• SPRAVATO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: TREATMENT-RESISTANT DEPRESSION (TRD), MAJOR DEPRESSIVE DISORDER (MDD): PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST. |
| Coverage Duration | INITIAL: TRD: 3 MONTHS. MDD: 4 WEEKS. RENEWAL: TRD, MDD: 12 MONTHS. |
| Other Criteria | INITIAL: TRD: 1) NON-PSYCHOTIC, UNIPOLAR DEPRESSION, 2) NO ACTIVE SUBSTANCE ABUSE, AND 3) ADEQUATE TRIAL (AT LEAST 4 WEEKS) OF AT LEAST TWO ANTIDEPRESSANT AGENTS FROM DIFFERENT CLASSES THAT ARE INDICATED FOR DEPRESSION. MDD: 1) NON-PSYCHOTIC, UNIPOLAR DEPRESSION, AND 2) NO ACTIVE SUBSTANCE ABUSE. RENEWAL: TRD, MDD: DEMONSTRATED CLINICAL BENEFIT (IMPROVEMENT IN DEPRESSION) COMPARED TO BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ETANERCEPT

Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE OR GENITAL AREA. |
| Age Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), PSORIATIC ARTHRITIS (PSA): 18 YEARS OR OLDER. |
| Prescriber Restrictions | INITIAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), AS: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSA: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|--|
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE- MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE: IS REQUIRED. PJIA, PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. RENEWAL: RA, PJIA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ETEPLIRSEN

Products Affected

• EXONDYS-51

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | DMD: INITIAL: PATIENT IS AMBULATORY AND CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS. RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E., PULMONARY OR CARDIAC FUNCTION). THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EVEROLIMUS-AFINITOR

Products Affected

• everolimus (antineoplastic) oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EVEROLIMUS-AFINITOR DISPERZ

Products Affected

• everolimus (antineoplastic) oral tablet for suspension

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FECAL MICROBIOTA CAPSULE

Products Affected

• VOWST

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 30 DAYS |
| Other Criteria | CLOSTRIDIOIDES DIFFICILE INFECTION (CDI): 1) HAS NOT PREVIOUSLY RECEIVED VOWST: COMPLETION OF ANTIBIOTIC TREATMENT FOR RECURRENT CDI (AT LEAST 3 CDI EPISODES), OR 2) PREVIOUSLY RECEIVED VOWST: (A) TREATMENT FAILURE (DEFINED AS THE PRESENCE OF CDI DIARRHEA WITHIN 8 WEEKS OF FIRST DOSE OF VOWST AND A POSITIVE STOOL TEST FOR C. DIFFICILE), AND (B) HAS NOT RECEIVED MORE THAN ONE TREATMENT COURSE OF VOWST WHICH WAS AT LEAST 12 DAYS AND NOT MORE THAN 8 WEEKS PRIOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FEDRATINIB

Products Affected

INREBIC

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | MYELOFIBROSIS: INITIAL: TRIAL OF OR CONTRAINDICATION TO JAKAFI (RUXOLITINIB). RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FENFLURAMINE

Products Affected

FINTEPLA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: DRAVET SYNDROME, LENNOX-GASTAUT SYNDROME (LGS): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | DRAVET SYNDROME: INITIAL/RENEWAL: 12 MONTHS. LGS: 12 MONTHS. |
| Other Criteria | INITIAL: LGS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING ANTIEPILEPTIC MEDICATIONS: RUFINAMIDE, FELBAMATE, CLOBAZAM, TOPIRAMATE, LAMOTRIGINE, CLONAZEPAM. RENEWAL: DRAVET SYNDROME: PATIENT HAS SHOWN CONTINUED CLINICAL BENEFIT (E.G. REDUCTION OF SEIZURES, REDUCED LENGTH OF SEIZURES, SEIZURE CONTROL MAINTAINED). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FENTANYL CITRATE

Products Affected

• fentanyl citrate buccal lozenge on a handle

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CANCER RELATED PAIN: 1) CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO AT LEAST ONE IMMEDIATE- RELEASE ORAL OPIOID PAIN AGENT OR PATIENT HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FILGRASTIM-AAFI

Products Affected

NIVESTYM

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FILGRASTIM-AYOW

Products Affected

RELEUKO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FILGRASTIM-SNDZ

Products Affected

· ZARXIO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NIVESTYM. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINASTERIDE/TADALAFIL

Products Affected

ENTADFI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | BENIGN PROSTATIC HYPERPLASIA (BPH): 18 YEARS OF AGE OR OLDER |
| Prescriber Restrictions | |
| Coverage Duration | 26 WEEKS |
| Other Criteria | BPH: 1) TRIAL OF OR CONTRAINDICATION TO ONE 5- ALPHA-REDUCTASE INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO TADALAFIL 2.5MG OR TADALAFIL 5MG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINERENONE

Products Affected

KERENDIA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINGOLIMOD

Products Affected

- fingolimod GILENYA ORAL CAPSULE 0.25 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINGOLIMOD LAURYL SULFATE

Products Affected

· TASCENSO ODT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | MULTIPLE SCLEROSIS (MS): (1) UNABLE TO SWALLOW FINGOLIMOD CAPSULES, AND (2) TRIAL OF OR CONTRAINDICATION TO FINGOLIMOD CAPSULES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FOSTAMATINIB

Products Affected

TAVALISSE

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | ITP: RENEWAL: PATIENT HAS SHOWN A CLINICAL RESPONSE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FREMANEZUMAB-VFRM

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | MIGRAINE PREVENTION: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: 1) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY, AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FUTIBATINIB

Products Affected

• LYTGOBI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INTRAHEPATIC CHOLANGIOCARCINOMA (ICCA): COMPLETE A COMPREHENSIVE OPHTHALMOLOGICAL EXAMINATION, INCLUDING OPTICAL COHERENCE TOMOGRAPHY (OCT), PRIOR TO THE INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GALCANEZUMAB-GNLM

Products Affected

EMGALITY PEN

- 3)
- EMGALITY SYRINGE SUBCUTANEOUS SYRINGE 120 MG/ML, 300 MG/3 ML (100 MG/ML X

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: MIGRAINE PREVENTION: 6 MOS. EPISODIC CLUSTER HEADACHE: 3 MOS. RENEWAL (ALL): 12 MOS. |
| Other Criteria | INITIAL: MIGRAINE PREVENTION: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL. RENEWAL: MIGRAINE PREVENTION: 1) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY, AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. EPISODIC CLUSTER HEADACHE: IMPROVEMENT IN EPISODIC CLUSTER HEADACHE FREQUENCY AS COMPARED TO BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GANAXOLONE

Products Affected

ZTALMY

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GEFITINIB

Products Affected

• gefitinib

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC NSCLC WITH EGFR MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GILTERITINIB

Products Affected

XOSPATA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GIVOSIRAN

Products Affected

GIVLAARI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: GENETIC CONFIRMATION OF MUTATION OR ELEVATED URINARY OR PLASMA PBG (PORPHOBILINOGEN) OR ALA (AMINOLEVULINIC ACID). |
| Age Restrictions | |
| Prescriber Restrictions | ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GENETICIST, HEPATOLOGIST, HEMATOLOGIST, GASTROENTEROLOGIST, NEUROLOGIST, DERMATOLOGIST, OR A HEALTHCARE PROVIDER EXPERIENCED IN MANAGING AHP. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS |
| Other Criteria | AHP: INITIAL: EXPERIENCED TWO OR MORE AHP ATTACKS IN THE PAST 12 MONTHS. RENEWAL: 1) ACHIEVED OR MAINTAINED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED A LIVER TRANSPLANT. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLASDEGIB

Products Affected

• DAURISMO ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLATIRAMER

- glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml
- glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLECAPREVIR/PIBRENTASVIR

Products Affected

MAVYRET ORAL TABLET

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE, 3) 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, 4) PATIENT MUST NOT HAVE PRIOR FAILURE OF A DAA REGIMEN WITH NS5A INHIBITOR AND HCV PROTEASE INHIBITOR, AND 5) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C). |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

GLP1-DULAGLUTIDE

Products Affected

• TRULICITY

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLP1-SEMAGLUTIDE

- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG (2 MG/3 ML), 0.25 MG OR 0.5 MG(2 MG/1.5 ML), 1 MG/DOSE (4 MG/3 ML),
- 2 MG/DOSE (8 MG/3 ML)
 RYBELSUS

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLP1-TIRZEPATIDE

Products Affected

MOUNJARO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLYCEROL PHENYLBUTYRATE

Products Affected

RAVICTI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | UREA CYCLE DISORDER (UCD): INITIAL: DIAGNOSIS IS CONFIRMED BY ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | UCD: INITIAL: TRIAL OF OR CONTRAINDICATION TO SODIUM PHENYLBUTYRATE. RENEWAL: PATIENT HAS CLINICAL BENEFIT FROM BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GOSERELIN

Products Affected

· ZOLADEX

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | ENDOMETRIOSIS: DIAGNOSIS IS CONFIRMED VIA SURGICAL OR DIRECT VISUALIZATION (E.G., PELVIC ULTRASOUND) OR HISTOPATHOLOGICAL CONFIRMATION (E.G., LAPAROSCOPY OR LAPAROTOMY) IN THE LAST 10 YEARS. |
| Age Restrictions | |
| Prescriber Restrictions | ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST. |
| Coverage Duration | STAGE B2-C PROSTATIC CARCINOMA: 4 MOS. ENDOMETRIOSIS: 6 MOS PER LIFETIME. ALL OTHERS: 12 MONTHS. |
| Other Criteria | ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 6 MONTHS OF TREATMENT PER LIFETIME. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH CONCENTRATION ORAL OPIOID SOLUTIONS

- morphine concentrate oral solution
- oxycodone oral concentrate

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | OPIOID TOLERANT: 12 MONTHS. HOSPICE, PALLIATIVE CARE OR END OF LIFE CARE: LIFETIME. |
| Other Criteria | 1) OPIOID TOLERANT (I.E. PREVIOUS USE OF 60 MG ORAL MORPHINE PER DAY, 25 MCG TRANSDERMAL FENTANYL PER HOUR, 30 MG ORAL OXYCODONE PER DAY, 8 MG ORAL HYDROMORPHONE PER DAY, 25 MG ORAL OXYMORPHONE PER DAY, 60 MG ORAL HYDROCODONE PER DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID) AND HAS TROUBLE SWALLOWING OPIOID TABLETS, CAPSULES, OR LARGE VOLUMES OF LIQUID, OR 2) ENROLLED IN HOSPICE OR PALLIATIVE CARE OR END OF LIFE CARE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - CARBINOXAMINE

- carbinoxamine maleate oral liquid
- carbinoxamine maleate oral tablet 4 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - CYPROHEPTADINE

Products Affected

• cyproheptadine

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - CLEMASTINE

Products Affected

• clemastine oral tablet 2.68 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - PROMETHAZINE

- promethazine injection solution
- promethazine oral
- promethazine rectal
- promethegan

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRURITUS/URTICARIA/SEASONAL/PERENNIAL ALLERGY: 1) TRIAL OF OR CONTRAINDICATION TO A NON- SEDATING ANTIHISTAMINE SUCH AS LEVOCETIRIZINE, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. NAUSEA AND VOMITING: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH-RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS REQUIRE PHYSICIAN ATTESTATION THAT REQUESTED MEDICATION IS USED TO TREAT A DIAGNOSIS UNRELATED TO THE TERMINAL ILLNESS OR RELATED CONDITION, AND ARE APPROVED WITHOUT TRIAL OF FORMULARY ALTERNATIVES NOR REQUIRING PRESCRIBER ACKNOWLEDGEMENT. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - SCOPOLAMINE

Products Affected

• scopolamine base

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS REQUIRE PHYSICIAN ATTESTATION THAT REQUESTED MEDICATION IS USED TO TREAT A DIAGNOSIS UNRELATED TO THE TERMINAL ILLNESS OR RELATED CONDITION, AND ARE APPROVED WITHOUT REQUIRING PRESCRIBER ACKNOWLEDGEMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY -**BARBITURATE COMBINATIONS**

- ascomp with codeine
- butalbital-acetaminop-caf-cod
- butalbital-acetaminophen oral tablet 50-325 codeine-butalbital-asa-caff
- butalbital-acetaminophen-caff oral capsule 50-325-40 mg
- butalbital-acetaminophen-caff oral tablet
- butalbital-aspirin-caffeine
- tencon
- zebutal

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - CONJUGATED ESTROGEN

Products Affected

• PREMARIN ORAL

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HYPOESTROGENISM TREATMENT, PALLIATIVE TREATMENT, AND HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - DIPYRIDAMOLE

Products Affected

• dipyridamole oral

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - DISOPYRAMIDE

Products Affected

• disopyramide phosphate oral capsule

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ENDOCRINE - SULFONYLUREAS

- glyburide
- glyburide micronized
- glyburide-metformin

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF GLIMEPIRIDE, GLIPIZIDE, OR PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL

Products Affected

• dotti

• lyllana

- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HYPOESTROGENISM TREATMENT, PALLIATIVE TREATMENT, AND HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL-NORETHINDRONE

- amabelz
- estradiol-norethindrone acet oral tablet 0.5-0.1 mg
- mimvey

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS, AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HYPOESTROGENISM TREATMENT AND HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-BAZEDOXIFENE

Products Affected

• DUAVEE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-MEDROXYPROGESTERONE

- PREMPHASE
- PREMPRO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - KETOROLAC

Products Affected

- ketorolac injection cartridge
- ketorolac injection solution 15 mg/ml, 30 mg/ml, 30 mg/ml (1 ml)
- ketorolac injection syringe 15 mg/ml, 30

mg/ml

- ketorolac intramuscular solution
- ketorolac intramuscular syringe
- ketorolac oral

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 30 DAYS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - NORETHINDRONE-ESTRADIOL

- fyavolv
- jinteli
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY - SKELETAL MUSCLE RELAXANTS

- chlorzoxazone oral tablet 250 mg, 500 mg, 750 mg
- cyclobenzaprine oral tablet 10 mg, 5 mg
- methocarbamol oral tablet 500 mg, 750 mg

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED A HIGH RISK MEDICATION FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY-ANTICHOLINERGICS- DIPHENHYDRAMINE ELIXIR

Products Affected

• diphenhydramine hcl oral elixir

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRURITUS OR URTICARIA: TRIAL OF OR CONTRAINDICATION TO A NON-SEDATING ANTIHISTAMINE SUCH AS LEVOCETIRIZINE. INSOMNIA: TRIAL OF SILENOR AND BELSOMRA. MOTION SICKNESS AND ANTIPARKINSONISM: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS AND ANAPHYLACTIC REACTIONS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY-DIPHENOXYLATE-ATROPINE

Products Affected

• diphenoxylate-atropine

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY-INDOMETHACIN

- indomethacin oral capsule 25 mg, 50 mg
- indomethacin oral capsule, extended release

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY-MEGESTROL

- megestrol oral suspension 400 mg/10 ml (40 mg/ml)
- megestrol oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK DRUGS IN THE ELDERLY-PAROXETINE

- paroxetine hcl oral suspension
- paroxetine hcl oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH RISK MEDICATIONS IN THE ELDERLY-PHENOBARBITAL

Products Affected

• phenobarbital

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | FOR TREATMENT OF EPILEPSY/SEIZURES IN PATIENTS WHO ARE NEWLY PRESCRIBED PHENOBARBITAL: PATIENT HAS NOT RESPONDED TO AT LEAST ONE ANTICONVULSANT OR PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HISTRELIN-SUPPRELIN LA

Products Affected

SUPPRELIN LA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

IBRUTINIB

Products Affected

• IMBRUVICA ORAL CAPSULE 140 MG, 70 MG

280 MG, 420 MG

- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG,

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: BRUKINSA, WHERE INDICATIONS ALIGN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IBUPROFEN-FAMOTIDINE

Products Affected

• ibuprofen-famotidine

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TRIAL OF ONE OF THE FOLLOWING GENERIC, FEDERAL LEGEND HISTAMINE H2-RECEPTOR ANTAGONISTS: FAMOTIDINE, CIMETIDINE, OR NIZATIDINE, AND TRIAL OF GENERIC, FEDERAL LEGEND IBUPROFEN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ICATIBANT

- icatibant
- sajazir

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEREDITARY ANGIOEDEMA (HAE): DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | HAE: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR HEMATOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | HAE: NO CONCURRENT USE WITH OTHER MEDICATIONS FOR TREATMENT OF ACUTE HAE ATTACKS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IDELALISIB

Products Affected

• ZYDELIG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IMATINIB

Products Affected

• imatinib oral tablet 100 mg, 400 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 36 MONTHS. ALL OTHER DIAGNOSES: 12 MONTHS. |
| Other Criteria | PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA: PATIENT HAS NOT RECEIVED A PREVIOUS TREATMENT WITH ANOTHER TYROSINE KINASE INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INFIGRATINIB

Products Affected

• TRUSELTIQ

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | CHOLANGIOCARCINOMA: COMPREHENSIVE OPHTHALMOLOGICAL EXAMINATION, INCLUDING OPTICAL COHERENCE TOMOGRAPHY (OCT), WILL BE COMPLETED PRIOR TO INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INFLIXIMAB

Products Affected

• infliximab

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO BOTH OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INFLIXIMAB-ABDA

Products Affected

RENFLEXIS

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO BOTH OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, YELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INFLIXIMAB-AXXQ

Products Affected

• AVSOLA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO BOTH OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INFLIXIMAB-DYYB

Products Affected

INFLECTRA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO BOTH OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INTERFERON FOR MS-AVONEX

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INTERFERON FOR MS-BETASERON

Products Affected

• BETASERON SUBCUTANEOUS KIT

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INTERFERON FOR MS-PLEGRIDY

Products Affected

 PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML

• PLEGRIDY SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INTERFERON GAMMA-1B

Products Affected

ACTIMMUNE

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: CHRONIC GRANULOMATOUS DISEASE (CGD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR IMMUNOLOGIST. SEVERE MALIGNANT OSTEOPETROSIS (SMO): PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | RENEWAL: CGD, SMO: 1) DEMONSTRATED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED HEMATOPOIETIC CELL TRANSPLANTATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IPILIMUMAB

Products Affected

• YERVOY

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: UNRESECT/MET MEL: 4MO, RCC/CRC/HCC: 3MO, ALL OTHERS: 12MO. INITIAL/RENEWAL: CUTAN MEL: 6MO |
| Other Criteria | RENEWAL: ADJUVANT CUTANEOUS MELANOMA: NO EVIDENCE OF DISEASE RECURRENCE (DEFINED AS THE APPEARANCE OF ONE OR MORE NEW MELANOMA LESIONS: LOCAL, REGIONAL OR DISTANT METASTASIS). THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ITRACONAZOLE SOLUTION

Products Affected

• itraconazole oral solution

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | ESOPHAGEAL CANDIDIASIS AND OROPHARYNGEAL CANDIDIASIS: TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IVACAFTOR

Products Affected

KALYDECO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS |
| Age Restrictions | |
| Prescriber Restrictions | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT |
| Coverage Duration | INITIAL: 12 MONTHS. RENEWAL: LIFETIME |
| Other Criteria | CF: INITIAL: NOT HOMOZYGOUS FOR F508DEL MUTATION IN CFTR GENE. RENEWAL: 1) MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR 2) REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IVOSIDENIB

Products Affected

• TIBSOVO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IXAZOMIB

Products Affected

NINLARO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LANADELUMAB

Products Affected

• TAKHZYRO SUBCUTANEOUS SOLUTION

(150 MG/ML)

 TAKHZYRO SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR HEMATOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LANREOTIDE

Products Affected

• lanreotide

ML

 SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 120 MG/0.5 ML, 60 MG/0.2 ML, 90 MG/0.3

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | ACROMEGALY: INITIAL: THERAPY IS PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | ACROMEGALY: INITIAL: 3 MOS, RENEWAL: 12 MOS.GEP- NETS, CARCINOID SYNDROME: 12 MOS. |
| Other Criteria | ACROMEGALY: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE GENERIC OCTREOTIDE INJECTION. RENEWAL: 1) REDUCTION, NORMALIZATION, OR MAINTENANCE OF IGF-1 LEVELS BASED ON AGE AND GENDER, AND 2) IMPROVEMENT OR SUSTAINED REMISSION OF CLINICAL SYMPTOMS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LAPATINIB

Products Affected

• lapatinib

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LAROTRECTINIB

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

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | APPROVAL FOR VITRAKVI ORAL SOLUTION: TRIAL OF VITRAKVI CAPSULES OR PATIENT IS UNABLE TO TAKE CAPSULE FORMULATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LEDIPASVIR-SOFOSBUVIR

- HARVONI ORAL PELLETS IN PACKET 33.75-150 MG, 45-200 MG
- HARVONI ORAL TABLET

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, AND 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING: CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, ROSUVASTATIN, TIPRANAVIR/RITONAVIR, SOFOSBUVIR (AS A SINGLE AGENT), EPCLUSA, ZEPATIER, MAVYRET, OR VOSEVI. REQUESTS FOR HARVONI 45MG-200MG PELLETS: PATIENT IS UNABLE TO SWALLOW TABLETS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LENALIDOMIDE

Products Affected

lenalidomide

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LENVATINIB

Products Affected

LENVIMA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LETERMOVIR

- PREVYMIS INTRAVENOUS SOLUTION 240 MG/12 ML, 480 MG/24 ML
- PREVYMIS ORAL

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | HSCT: NOT AT RISK FOR LATE CMV: 4 MOS, AT RISK FOR LATE CMV: 7 MOS. KIDNEY TRANSPLANT: 7 MOS. |
| Other Criteria | HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT): 1) THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 28 POST TRANSPLANT, AND 2) WILL NOT RECEIVE THE MEDICATION BEYOND 100 DAYS POST TRANSPLANT IF NOT AT RISK FOR LATE CYTOMEGALOVIRUS (CMV) INFECTION AND DISEASE, OR BEYOND 200 DAYS POST TRANSPLANT IF AT RISK FOR LATE CMV INFECTION AND DISEASE. KIDNEY TRANSPLANT: 1) THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 7 POST TRANSPLANT, AND 2) WILL NOT RECEIVE THE MEDICATION BEYOND 200 DAYS POST TRANSPLANT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LEUPROLIDE

Products Affected

• leuprolide subcutaneous kit

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | PROSTATE CANCER: 12 MONTHS. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LEUPROLIDE DEPOT

Products Affected

• leuprolide (3 month)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LEUPROLIDE-ELIGARD

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LEUPROLIDE-LUPRON DEPOT

- · LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ENDOMETRIOSIS: DIAGNOSIS IS CONFIRMED VIA SURGICAL OR DIRECT VISUALIZATION (E.G., PELVIC ULTRASOUND) OR HISTOPATHOLOGICAL CONFIRMATION (E.G., LAPAROSCOPY OR LAPAROTOMY) IN THE LAST 10 YEARS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST. |
| Coverage Duration | PROSTATE CA: 12 MOS. UTERINE FIBROIDS: 3 MOS. ENDOMETRIOSIS: INITIAL/RENEWAL: 6 MOS. |
| Other Criteria | INITIAL: ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF TREATMENT PER LIFETIME. RENEWAL: ENDOMETRIOSIS: 1) IMPROVEMENT OF PAIN RELATED TO ENDOMETRIOSIS WHILE ON THERAPY, 2) RECEIVING CONCOMITANT ADD-BACK THERAPY (I.E., COMBINATION ESTROGEN-PROGESTIN OR PROGESTIN-ONLY CONTRACEPTIVE PREPARATION), 3) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 4) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF TREATMENT PER LIFETIME. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

LEUPROLIDE-LUPRON DEPOT-PED

- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

LEVODOPA

Products Affected

• INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | PD: INITIAL: 1) NOT CURRENTLY TAKING MORE THAN 1600MG OF LEVODOPA PER DAY, AND 2) PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF INBRIJA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

L-GLUTAMINE

Products Affected

ENDARI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | SICKLE CELL DISEASE(SCD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST |
| Coverage Duration | INITIAL: 12 MONTHS. RENEWAL: LIFETIME. |
| Other Criteria | SCD: INITIAL: AGES 18 YEARS OR OLDER: 1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, 2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR 3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME. AGES 5 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: MAINTAINED OR EXPERIENCED A REDUCTION IN ACUTE COMPLICATIONS OF SCD. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE OINTMENT

Products Affected

• lidocaine topical ointment

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE PATCH

- lidocaine topical adhesive patch,medicated 5
- · ZTLIDO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE PRILOCAINE

Products Affected

• lidocaine-prilocaine topical cream

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE SOLUTION

Products Affected

• lidocaine hcl mucous membrane solution 4 % (40 mg/ml)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LOMITAPIDE

Products Affected

 JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 5 MG, 60 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST. |
| Coverage Duration | 12 MONTHS |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | 1) DIAGNOSIS DETERMINED BY A) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, OR B) DUTCH LIPID NETWORK CRITERIA SCORE OF 8 OR GREATER, OR C) CLINICAL DIAGNOSIS BASED ON A HISTORY OF AN UNTREATED LDL-C CONCENTRATION GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YEARS OF AGE, OR EVIDENCE OF HEFH IN BOTH PARENTS. 2) LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL WHILE ON MAXIMAL DRUG TREATMENT. 3) TRIAL OF EVOLOCUMAB UNLESS THE PATIENT HAS NON-FUNCTIONING LDL RECEPTORS. 4) MEETS ONE OF THE FOLLOWING: A) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, B) TAKING A MAXIMALLY TOLERATED DOSE OF ANY STATIN FOR A DURATION OF AT LEAST 8 WEEKS GIVEN THAT THE PATIENT CANNOT TOLERATE A HIGH-INTENSITY STATIN, C) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), D) STATIN INTOLERANCE, OR E) TRIAL OF ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LONCASTUXIMAB TESIRINE-LPYL

Products Affected

ZYNLONTA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LORLATINIB

Products Affected

 LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUMACAFTOR-IVACAFTOR

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CYSTIC FIBROSIS (CF): CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CF. |
| Age Restrictions | |
| Prescriber Restrictions | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CF EXPERT. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: LIFETIME. |
| Other Criteria | CF: RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUMASIRAN

Products Affected

· OXLUMO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MACITENTAN

Products Affected

• OPSUMIT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MARGETUXIMAB-CMKB

Products Affected

MARGENZA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MECHLORETHAMINE

Products Affected

VALCHLOR

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MEPOLIZUMAB

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

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN PULMONARY OR ALLERGY MEDICINE. NASAL POLYPS: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: ASTHMA: 4 MO. NASAL POLYPS: 6 MO. OTHERS: 12 MO. RENEWAL: NASAL POLYPS, ASTHMA: 12 MO. |

| PA Criteria | Criteria Details |
|----------------|---|
| Other Criteria | INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. NASAL POLYPS: PREVIOUS 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID. RENEWAL: ASTHMA: 1) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEVI FROM |
| Indications | PRETREATMENT BASELINE. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE. All FDA-approved Indications. |
| Off Label Uses | |

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

METHYLNALTREXONE

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE 12 MG/0.6 ML, 8 MG/0.4 ML

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | ADVANCED ILLNESS: 6 MONTHS. CHRONIC NON-CANCER PAIN: 12 MONTHS. |
| Other Criteria | CHRONIC NON-CANCER PAIN: 1) HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA) |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

METHYLNALTREXONE ORAL

Products Affected

· RELISTOR ORAL

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | OPIOID INDUCED CONSTIPATION WITH CHRONIC NON-CANCER PAIN: 1) HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA) |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MIDOSTAURIN

Products Affected

RYDAPT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | ACUTE MYELOID LEUKEMIA: 6 MONTHS. ADVANCED SYSTEMIC MASTOCYTOSIS: 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MIFEPRISTONE

Products Affected

KORLYM

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CUSHINGS SYNDROME (CS): INITIAL: DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: 1) 24-HR URINE FREE CORTISOL (2 OR MORE TESTS TO CONFIRM), 2) OVERNIGHT 1MG DEXAMETHASONE TEST, OR 3) LATE NIGHT SALIVARY CORTISOL (2 OR MORE TESTS TO CONFIRM). |
| Age Restrictions | |
| Prescriber Restrictions | CS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL AND RENEWAL: 12 MONTHS. |
| Other Criteria | CS: INITIAL: HYPERCORTISOLISM IS NOT A RESULT OF CHRONIC GLUCOCORTICOIDS. RENEWAL: 1) CONTINUES TO HAVE IMPROVEMENT OF GLUCOSE TOLERANCE OR STABLE GLUCOSE TOLERANCE (E.G., REDUCED A1C, IMPROVED FASTING GLUCOSE, ETC.), 2) CONTINUES TO HAVE TOLERABILITY TO KORLYM, AND 3) CONTINUES TO NOT BE A CANDIDATE FOR SURGICAL TREATMENT OR HAS FAILED SURGERY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MIGALASTAT

Products Affected

GALAFOLD

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | FABRY DISEASE: INITIAL SYMPTOMATIC OR EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS. |
| Age Restrictions | |
| Prescriber Restrictions | FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS. |
| Coverage Duration | INITIAL: 6 MOS. RENEWAL: 12 MOS. |
| Other Criteria | FABRY DISEASE: INITIAL: NOT CONCURRENTLY USING ENZYME REPLACEMENT THERAPY (I.E. FABRAZYME). RENEWAL: 1) IMPROVEMENT OR STABILIZATION, AND 2) NOT CONCURRENTLY USING ENZYME REPLACEMENT THERAPY (I.E. FABRAZYME). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MIGLUSTAT

Products Affected

• miglustat

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MILTEFOSINE

Products Affected

• IMPAVIDO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MOBOCERTINIB

Products Affected

EXKIVITY

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MOSUNETUZUMAB-AXGB

Products Affected

LUNSUMIO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA: INITIAL: 6 MONTHS. RENEWAL: 7 MONTHS. |
| Other Criteria | RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA: RENEWAL: 1) HAS ACHIEVED A PARTIAL RESPONSE TO TREATMENT, AND 2) HAS NOT PREVIOUSLY RECEIVED MORE THAN 17 CYCLES OF TREATMENT. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NAFARELIN

Products Affected

• SYNAREL

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ENDOMETRIOSIS: DIAGNOSIS IS CONFIRMED VIA SURGICAL OR DIRECT VISUALIZATION (E.G., PELVIC ULTRASOUND) OR HISTOPATHOLOGICAL CONFIRMATION (E.G., LAPAROSCOPY OR LAPAROTOMY) IN THE LAST 10 YEARS. CENTRAL PRECOCIOUS PUBERTY (CPP): FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ENDOMETRIOSIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST. CPP: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | ENDOMETRIOSIS: 6 MONTHS. CPP: INITIAL/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: ENDOMETRIOSIS: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, 2) TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING PREPARATION, AND 3) HAS NOT RECEIVED A TOTAL OF 6 MONTHS OF TREATMENT PER LIFETIME. CPP: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: CPP: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NARCOLEPSY AGENTS

Products Affected

- armodafinil
- modafinil oral tablet 100 mg, 200 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NATALIZUMAB

Products Affected

TYSABRI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | MULTIPLE SCLEROSIS (MS): 12 MOS. CD: INITIAL: 6 MOS, RENEWAL: 12 MOS. |
| Other Criteria | INITIAL: MS: TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF MS. CD: TRIAL OF OR CONTRAINDICATION TO BOTH OF THE FOLLOWING PREFERRED AGENTS: HUMIRA AND STELARA. RENEWAL: CD: 1) RECEIVED AT LEAST 12 MONTHS OF THERAPY WITH TYSABRI AND HAS NOT REQUIRED MORE THAN 3 MONTHS OF CORTICOSTEROID USE WITHIN THE PAST 12 MONTHS TO CONTROL THEIR CROHNS DISEASE WHILE ON TYSABRI, OR 2) HAS ONLY RECEIVED 6 MONTHS OF THERAPY WITH TYSABRI AND HAS TAPERED OFF CORTICOSTEROIDS DURING THE FIRST 24 WEEKS OF TYSABRI THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NAXITAMAB-GQGK

Products Affected

DANYELZA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NERATINIB MALEATE

Products Affected

NERLYNX

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | EARLY-STAGE (STAGE I-III) BREAST CANCER: MEDICATION IS BEING REQUESTED WITHIN 2 YEARS OF COMPLETING THE LAST TRASTUZUMAB DOSE. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NILOTINIB

Products Affected

 TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | PREVIOUSLY TREATED CML: MUTATIONAL ANALYSIS PRIOR TO INITIATION AND TASIGNA IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NINTEDANIB

Products Affected

• OFEV

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) BASELINE FORCED VITAL CAPACITY (FVC) AT LEAST 50% OF PREDICTED VALUE. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 40% OF PREDICTED VALUE. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (PF-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 45% OF PREDICTED VALUE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL (ALL INDICATIONS): 12 MOS. |

| PA Criteria | Criteria Details |
|------------------------|--|
| Other Criteria | INITIAL: IPF: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ESBRIET (PIRFENIDONE). SSC-ILD: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., HEART FAILURE/FLUID OVERLOAD, DRUG-INDUCED LUNG TOXICITY, RECURRENT ASPIRATION), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ACTEMRA SUBQ. PF-ILD: LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENED/PROGRESSED DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILD (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE). RENEWAL: IPF, SSC-ILD, PF-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIRAPARIB

Products Affected

- · ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: 1) ZEJULA WILL BE USED AS MONOTHERAPY, AND 2) ZEJULA IS STARTED NO LATER THAN 8 WEEKS AFTER THE MOST RECENT PLATINUM-CONTAINING REGIMEN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIRAPARIB/ABIRATERONE

Products Affected

AKEEGA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIRSEVIMAB-ALIP

Products Affected

• BEYFORTUS

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | RESPIRATORY SYNCYTIAL VIRUS (RSV) PREVENTION: 1) HAS NOT COMPLETED A COURSE OF SYNAGIS OR HAS NOT RECEIVED A DOSE OF SYNAGIS IN THE PAST 30 DAYS, AND WILL NOT RECEIVE FURTHER DOSES OF SYNAGIS WITHIN THE SAME RSV SEASON, AND 2) HAS NOT RECEIVED MORE THAN 2 DOSES OF BEYFORTUS PER LIFETIME, UNLESS HAS UNDERGONE OR WILL UNDERGO A CARDIAC SURGERY WITH CARDIOPULMONARY BYPASS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NITISINONE

Products Affected

- nitisinone
- ORFADIN ORAL SUSPENSION

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HEREDITARY TYROSINEMIA TYPE 1 (HT-1): INITIAL: DIAGNOSIS CONFIRMED BY ELEVATED URINARY OR PLASMA SUCCINYLACETONE LEVELS OR A MUTATION IN THE FUMARYLACETOACETATE HYDROLASE GENE. RENEWAL: URINARY OR PLASMA SUCCINYLACETONE LEVELS HAVE DECREASED FROM BASELINE WHILE ON TREATMENT WITH NITISINONE. |
| Age Restrictions | |
| Prescriber Restrictions | HT-1: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | HT-1: INITIAL: ORFADIN SUSPENSION: TRIAL OF OR CONTRAINDICATION TO PREFERRED NITISINONE TABLETS OR CAPSULES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIVOLUMAB

Products Affected

· OPDIVO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNRESECTABLE OR METASTATIC MELANOMA: NO CONCURRENT USE WITH TARGETED THERAPY (I.E., BRAF INHIBITORS, MEK INHIBITORS, AND NTRK INHIBITORS). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIVOLUMAB-RELATLIMAB-RMBW

Products Affected

OPDUALAG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OBETICHOLIC ACID

Products Affected

· OCALIVA

| PA Criteria | Criteria Details |
|------------------------|--|
| Exclusion | PRIMARY BILIARY CHOLANGITIS (PBC): |
| Criteria | INITIAL/RENEWAL: COMPLETE BILIARY OBSTRUCTION. |
| Required Medical | PBC: INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE |
| Information | FOLLOWING: 1) ALKALINE PHOSPHATASE LEVEL OF AT |
| | LEAST 1.5 TIMES THE UPPER LIMIT OF NORMAL, 2) |
| | PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES AT A |
| | TITER OF 1:40 OR HIGHER, OR 3) HISTOLOGIC EVIDENCE |
| | OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND |
| | DESTRUCTION OF INTERLOBULAR BILE DUCTS. |
| Age Restrictions | |
| Prescriber | PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION |
| Restrictions | WITH A GASTROENTEROLOGIST OR HEPATOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | PBC: INITIAL: USED IN COMBINATION WITH |
| | URSODEOXYCHOLIC ACID IN A PATIENT WITH AN |
| | INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID, |
| | OR AS MONOTHERAPY IN A PATIENT WHO IS UNABLE TO |
| | TOLERATE URSODEOXYCHOLIC ACID. RENEWAL: |
| | CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OCRELIZUMAB

Products Affected

• OCREVUS

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF RELAPSING FORMS OF MS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OFATUMUMAB-SQ

Products Affected

KESIMPTA PEN

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OLANZAPINE/SAMIDORPHAN

Products Affected

LYBALVI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | SCHIZOPHRENIA/BIPOLAR I: PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST |
| Coverage Duration | 12 MONTHS |
| Other Criteria | SCHIZOPHRENIA: (1) PATIENT IS AT HIGH RISK OF WEIGHT GAIN AND (2) TRIAL OF OR CONTRAINDICATION TO LATUDA OR ONE OF THE FOLLOWING ORAL ANTIPSYCHOTICS: RISPERIDONE, CLOZAPINE TABLET, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE. BIPOLAR I: (1) PATIENT IS AT HIGH RISK OF WEIGHT GAIN AND (2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING ORAL ANTIPSYCHOTICS: RISPERIDONE, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OLAPARIB

Products Affected

LYNPARZA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER: MEDICATION WILL BE USED AS MONOTHERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OLUTASIDENIB

Products Affected

REZLIDHIA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OMACETAXINE

Products Affected

• SYNRIBO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OMALIZUMAB

Products Affected

XOLAIR

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ASTHMA: POSITIVE SKIN PRICK OR BLOOD TEST (E.G., ELISA, FEIA) TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL GREATER THAN OR EQUAL TO 30 IU/ML. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL AND RENEWAL: CHRONIC SPONTANEOUS URTICARIA (CSU): PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE, DERMATOLOGY OR IMMUNOLOGY. INITIAL: NASAL POLYPS: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| Coverage Duration | INITIAL: ASTHMA: 4 MO. CSU, NASAL POLYPS: 6 MO. RENEWAL: ASTHMA, NASAL POLYPS: 12 MO. CSU: 6 MO. |

| PA Criteria | Criteria Details |
|----------------|--|
| Other Criteria | INITIAL: CSU: TRIAL OF OR CONTRAINDICATION TO A MAXIMALLY TOLERATED DOSE OF AN HI ANTI-HISTAMINE AND STILL EXPERIENCES HIVES ON MOST DAYS OF THE WEEK. NASAL POLYPS: 1) PREVIOUS 90 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED AGENT: NUCALA, DUPIXENT. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, 2) ONE OF THE FOLLOWING: (A) PATIENT EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) PATIENT HAS POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, 3) NOT CONCURRENTLY RECEIVING DUPIXENT OR ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. RENEWAL: CSU: DIAGNOSIS OF CSU. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE. ASTHMA: 1) NOT CONCURRENTLY RECEIVING DUPIXENT OR ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN ASTHMA |
| | IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

OPICAPONE

Products Affected

ONGENTYS

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | PARKINSONS DISEASE: 18 YEARS OF AGE OR OLDER |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OSIMERTINIB

Products Affected

TAGRISSO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | EGFR EXON 19 DELETIONS OR EXON 21 L858R MUTATIONS NON-SMALL CELL LUNG CANCER (NSCLC) AND METASTATIC NSCLC WITH EGFR T790M MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OXANDROLONE

Products Affected

oxandrolone

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | PROTEIN CATABOLISM, BONE PAIN: 1) MONITORED FOR PELIOSIS HEPATIS, LIVER CELL TUMORS, AND BLOOD LIPID CHANGES, 2) DOES NOT HAVE KNOWN OR SUSPECTED: CARCINOMA OF THE PROSTATE OR BREAST IN MALE PATIENTS, CARCINOMA OF THE BREAST IN FEMALES WITH HYPERCALCEMIA, NEPHROSIS (THE NEPHROTIC PHASE OF NEPHRITIS), OR HYPERCALCEMIA, AND 3) DOES NOT HAVE SEVERE HEPATIC DYSFUNCTION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PACRITINIB

Products Affected

· VONJO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | MYELOFIBROSIS: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PALBOCICLIB

Products Affected

• IBRANCE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: VERZENIO. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PALIVIZUMAB

Products Affected

SYNAGIS

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: GESTATIONAL AGE |
| Age Restrictions | INITIAL AND RENEWAL: LESS THAN 24 MONTHS OF AGE. |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA CONSISTENT WITH THE CDC RSV CENSUS REGIONAL TREND. SEE OTHER CRITERIA. |
| Other Criteria | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT RECOMMENDATIONS FROM THE AMERICAN ACADEMY OF PEDIATRICS FOR PALIVIZUMAB PROPHYLAXIS FOR RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTIONS AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION RSV CENSUS REGIONAL TREND. APPROVAL WILL BE FOR UP TO A MAXIMUM OF 5 MONTHS DEPENDENT UPON REMAINING LENGTH OF RESPIRATORY SYNCYTIAL VIRUS SEASON. RENEWAL: ADDITIONAL 1 MONTH OF TREATMENT FOR CARDIOPULMONARY BYPASS SURGERY DURING RSV PROPHYLAXIS SEASON. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PANOBINOSTAT

Products Affected

FARYDAK

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | MULTIPLE MYELOMA: RENEWAL: TOLERATED THE FIRST 8 CYCLES OF THERAPY WITHOUT UNRESOLVED SEVERE OR MEDICALLY SIGNIFICANT TOXICITY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PARATHYROID HORMONE

Products Affected

NATPARA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: 1) TRIAL OF OR CONTRAINDICATION TO CALCITRIOL, 2) HYPOPARATHYROIDISM IS NOT DUE TO A CALCIUM SENSING RECEPTOR (CSR) MUTATION, AND 3) HYPOPARATHYROIDISM IS NOT CONSIDERED ACUTE POST-SURGICAL HYPOPARATHYROIDISM. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PASIREOTIDE DIASPARTATE

Products Affected

SIGNIFOR

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | CUSHINGS DISEASE (CD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | CD: RENEWAL: 1) CONTINUED IMPROVEMENT OF CUSHINGS DISEASE, AND 2) MAINTAINED TOLERABILITY TO SIGNIFOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PAZOPANIB

Products Affected

VOTRIENT

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED SOFT TISSUE SARCOMA (STS): NOT USED FOR ADIPOCYTIC STS OR GASTROINTESTINAL STROMAL TUMORS (GIST) |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION - IV

Products Affected

• sildenafil (pulm.hypertension) intravenous

| PA Criteria | Criteria Details |
|-----------------------|--|
| Exclusion Criteria | |
| | |
| Required Medical | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: |
| Information | DIAGNOSIS CONFIRMED BY RIGHT HEART |
| | CATHETERIZATION WITH THE FOLLOWING |
| | PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE |
| | (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR |
| | LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) |
| | GREATER THAN 2 WOOD UNITS. |
| | OKLATER THAN 2 WOOD ONTIS. |
| Age Restrictions | |
| Prescriber | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION |
| Restrictions | WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage | INITIAL/RENEWAL: 12 MONTHS. |
| Duration | |
| Other Criteria | PAH: INITIAL: NOT CONCURRENTLY OR |
| | INTERMITTENTLY TAKING ORAL ERECTILE |
| | DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY |
| | ORGANIC NITRATES IN ANY FORM, OR GUANYLATE |
| | CYCLASE STIMULATORS. RENEWAL: 1) NOT |
| | CONCURRENTLY OR INTERMITTENTLY TAKING ORAL |
| | ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), |
| | ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE |
| | CYCLASE STIMULATORS, AND 2) (A) IMPROVEMENT |
| | FROM BASELINE IN THE 6-MINUTE WALK DISTANCE |
| | TEST, OR (B) REMAINS STABLE FROM BASELINE IN THE 6- |
| | MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. |
| | CLASS HAS REMAINED STABLE OR IMPROVED. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM - APGF

Products Affected

NYVEPRIA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM - CBQV

Products Affected

- UDENYCA
- UDENYCA AUTOINJECTOR

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO NYVEPRIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM - JMDB

Products Affected

• FULPHILA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO NYVEPRIA |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM-BMEZ

Products Affected

ZIEXTENZO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO NYVEPRIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM-NEULASTA ONPRO

Products Affected

NEULASTA ONPRO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY, ACUTE RADIATION EXPOSURE: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGFILGRASTIM-PBBK

Products Affected

FYLNETRA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON MYELOID MALIGNANCY: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO PREFERRED AGENT: NYVEPRIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGINTERFERON ALFA-2A

Products Affected

PEGASYS

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | CHRONIC HEPATITIS C VIRUS INFECTION. CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HEPATITIS B: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, OR PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (E.G., HEPATOLOGIST). |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGUNIGALSIDASE ALFA-IWXJ

Products Affected

ELFABRIO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | FABRY DISEASE: INITIAL: 1) SYMPTOMATIC OR EVIDENCE OF INJURY TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS, AND 2) ONE OF THE FOLLOWING: (A) FEMALES: GALACTOSIDASE ALPHA (GLA) GENE MUTATION VIA GENETIC TESTING, OR (B) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGVALIASE-PQPZ

Products Affected

• PALYNZIQ

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | PHENYLKETONURIA (PKU): INITIAL: NOT ON CONCURRENT TREATMENT WITH KUVAN. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NOT ON CONCURRENT TREATMENT WITH KUVAN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEGVISOMANT

Products Affected

SOMAVERT

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEMBROLIZUMAB

Products Affected

KEYTRUDA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNRESECTABLE OR METASTATIC MELANOMA: NO CONCURRENT USE WITH TARGETED THERAPY (I.E., BRAF INHIBITORS, MEK INHIBITORS, AND NTRK INHIBITORS). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEMIGATINIB

Products Affected

• PEMAZYRE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CHOLANGIOCARCINOMA, MYELOID/LYMPHOID NEOPLASMS: COMPREHENSIVE OPHTHALMOLOGICAL EXAMINATION, INCLUDING OPTICAL COHERENCE TOMOGRAPHY (OCT), WILL BE COMPLETED PRIOR TO INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PENICILLAMINE TABLET

Products Affected

• penicillamine oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CYSTINURIA: HAS NEPHROLITHIASIS AND ONE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTINE, 2) PRESENCE OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) FAMILY HISTORY OF CYSTINURIA AND POSITIVE CYANIDE-NITROPRUSSIDE SCREENING. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: WILSONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST. CYSTINURIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST. RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 12 MONTHS, RENEWAL: LIFETIME. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: WILSONS DISEASE: 1) LEIPZIG SCORE OF 4 OR GREATER. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS DISEASE, CYSTINURIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEXIDARTINIB

Products Affected

TURALIO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PIMAVANSERIN

Products Affected

NUPLAZID

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | PSYCHOSIS IN PARKINSONS DISEASE (PD): INITIAL: 18 YEARS OR OLDER |
| Prescriber Restrictions | PSYCHOSIS IN PD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, GERIATRICIAN, OR A BEHAVIORAL HEALTH SPECIALIST (E.G., PSYCHIATRIST). |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PSYCHOSIS IN PD: RENEWAL: IMPROVEMENT IN PSYCHOSIS SYMPTOMS FROM BASELINE AND DEMONSTRATES A CONTINUED NEED FOR TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PIRFENIDONE

Products Affected

- pirfenidone oral capsulepirfenidone oral tablet 267 mg, 534 mg, 801

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | IDIOPATHIC PULMONARY FIBROSIS (IPF): INITIAL: 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) PREDICTED FORCED VITAL CAPACITY (FVC) OF AT LEAST 50% AT BASELINE. |
| Age Restrictions | IPF: INITIAL: 18 YEARS OR OLDER. |
| Prescriber Restrictions | IPF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | IPF: INITIAL: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, OR CANCER). RENEWAL: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

PIRTOBRUTINIB

Products Affected

• JAYPIRCA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

POMALIDOMIDE

Products Affected

POMALYST

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PONATINIB

Products Affected

· ICLUSIG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CML: MUTATIONAL ANALYSIS PRIOR TO INITIATION AND ICLUSIG IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

POSACONAZOLE

Products Affected

posaconazole oral

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | OROPHARYNGEAL CANDIDIASIS (OPC): 3 MONTHS. PROPHYLAXIS: 6 MONTHS. TREATMENT: 12 WEEKS. |
| Other Criteria | POSACONAZOLE SUSPENSION ONLY: 1) OPC: TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE OR ITRACONAZOLE. 2) PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: INABILITY TO SWALLOW TABLETS. POSACONZOLE TABLETS ONLY: 1) TREATMENT OF INVASIVE ASPERGILLOSIS, 2) PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: AT HIGH RISK OF DEVELOPING THESE INFECTIONS DUE TO BEING SEVERELY IMMUNOCOMPROMISED. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

POSACONAZOLE-POWDERMIX

Products Affected

• NOXAFIL ORAL SUSP, DELAYED RELEASE FOR RECON

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 MONTHS |
| Other Criteria | PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: INABILITY TO SWALLOW TABLETS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PRALSETINIB

Products Affected

• GAVRETO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PRAMLINTIDE

Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TYPE I OR TYPE II DIABETES: REQUIRING INSULIN OR CONTINUOUS INSULIN INFUSION (INSULIN PUMP) FOR GLYCEMIC CONTROL |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PYRIMETHAMINE

Products Affected

• pyrimethamine

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | TOXOPLASMOSIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST. |
| Coverage Duration | TOXOPLASMOSIS: INITIAL: 8 WEEKS, RENEWAL: 6 MOS. |
| Other Criteria | 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

QUININE

Products Affected

• quinine sulfate

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

QUIZARTINIB

Products Affected

VANFLYTA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RAMUCIRUMAB

Products Affected

· CYRAMZA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

REGORAFENIB

Products Affected

STIVARGA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RELUGOLIX

Products Affected

ORGOVYX

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RESLIZUMAB

Products Affected

· CINQAIR

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | ASTHMA: INITIAL: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| Coverage Duration | ASTHMA: INITIAL: 4 MONTHS. RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, 3) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT, AND 4) NO CONCURRENT USE WITH XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. RENEWAL: 1) NO CONCURRENT USE WITH XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMARELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEVI FROM PRETREATMENT BASELINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RETIFANLIMAB-DLWR

Products Affected

ZYNYZ

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIBOCICLIB

Products Affected

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

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: VERZENIO, WHERE INDICATIONS ALIGN. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIBOCICLIB-LETROZOLE

Products Affected

 KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY(200 MG X 1)-2.5 MG, 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: VERZENIO. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIFAXIMIN

Products Affected

• XIFAXAN ORAL TABLET 200 MG, 550 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | TRAVELERS DIARRHEA/HE: 12 MOS. IBS-D: 8 WKS. |
| Other Criteria | RIFAXIMIN 550 MG TABLETS: HE: TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIMEGEPANT

Products Affected

NURTEC ODT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: ACUTE MIGRAINE TREATMENT: TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN). EPISODIC MIGRAINE PREVENTION: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL. RENEWAL: ACUTE MIGRAINE TREATMENT: 1) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR 2) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS. EPISODIC MIGRAINE PREVENTION: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION, AND 2) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY, MIGRAINE SEVERITY, OR MIGRAINE DURATION WITH THERAPY. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

RIOCIGUAT

Products Affected

ADEMPAS

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) (WHO GROUP 4): WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PAH, CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: PAH: NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. CTEPH: 1) NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS, AND 2) NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL: PAH, CTEPH: 1) NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS AND 2) (A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR (B) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE CLASS HAS REMAINED STABLE OR IMPROVED. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIPRETINIB

Products Affected

· QINLOCK

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RISDIPLAM

Products Affected

• EVRYSDI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | SPINAL MUSCULAR ATROPHY (SMA): INITIAL: GENE MUTATION ANALYSIS INDICATING MUTATIONS OR DELETIONS OF BOTH ALLELES OF THE SURVIVAL MOTOR NEURON 1 (SMN1) GENE. FOR PRESYMPTOMATIC PATIENTS: UP TO THREE COPIES OF SURVIVAL MOTOR NEURON 2 (SMN2) BASED ON NEWBORN SCREENING. |
| Age Restrictions | |
| Prescriber Restrictions | SMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROMUSCULAR SPECIALIST OR SMA SPECIALIST AT A SMA SPECIALTY CENTER. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | SMA: INITIAL: FOR SYMPTOMATIC PATIENTS: (1) BASELINE MOTOR FUNCTION ASSESSMENT BY A NEUROMUSCULAR SPECIALIST OR SMA SPECIALIST, AND (2) IF PATIENT RECEIVED GENE THERAPY, THE PATIENT HAD LESS THAN EXPECTED CLINICAL BENEFIT. RENEWAL: IMPROVED, MAINTAINED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN: (1) MOTOR FUNCTION ASSESSMENTS COMPARED TO BASELINE, OR (2) OTHER MUSCLE FUNCTION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB AND HYALURONIDASE HUMAN-SQ

Products Affected

· RITUXAN HYCELA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | FOLLICULAR LYMPHOMA (FL), DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): HAS RECEIVED OR WILL RECEIVE AT LEAST ONE FULL DOSE OF A RITUXIMAB PRODUCT BY INTRAVENOUS INFUSION PRIOR TO INITIATION OF RITUXIMAB AND HYALURONIDASE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB-ABBS

Products Affected

TRUXIMA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA: 12 MO. CLL: 6 MO. |
| Other Criteria | RA: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB-ARRX

Products Affected

RIABNI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, WG, MPA: 12 MO. CLL: 6 MO. |
| Other Criteria | RA: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB-PVVR

Products Affected

RUXIENCE

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | NHL, GPA, MPA: 12 MONTHS. CLL: 6 MONTHS. RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | RA: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ROMIPLOSTIM

Products Affected

• NPLATE

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| Coverage Duration | ITP: INITIAL: 4 MO, RENEWAL: 12 MO. HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME: 12 MO. |
| Other Criteria | ITP: INITIAL: TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. RENEWAL: CLINICAL RESPONSE TO THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ROPEGINTERFERON ALFA-2B-NJFT

Products Affected

BESREMI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RUCAPARIB

Products Affected

• RUBRACA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: ONE OF THE FOLLOWING: 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RUXOLITINIB

Products Affected

JAKAFI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | MYELOFIBROSIS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYCYTHEMIA VERA, GVHD: 12 MONTHS. |
| Other Criteria | MYELOFIBROSIS: RENEWAL: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SAFINAMIDE

Products Affected

XADAGO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SAPROPTERIN

Products Affected

- javygtor oral tablet,soluble sapropterin oral tablet,soluble

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 1 MONTH, RENEWAL 12 MONTHS. |
| Other Criteria | HYPERPHENYLALANINEMIA (HPA): INITIAL: NOT CONCURRENTLY USING PALYNZIQ. RENEWAL: 1) CONTINUES TO BENEFIT FROM TREATMENT, AND 2) NOT CONCURRENTLY USING PALYNZIQ. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SARILUMAB

Products Affected

KEVZARA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYMYALGIA RHEUMATICA (PMR): 12 MONTHS. |
| Other Criteria | RA: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SATRALIZUMAB-MWGE

Products Affected

ENSPRYNG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): INITIAL: PRESCRIBED BY AN OPHTHALMOLOGIST OR PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | NMOSD: INITIAL: 1) ONE OF THE FOLLOWING CORE CLINICAL CHARACTERISTIC: (A) OPTIC NEURITIS, (B) ACUTE MYELITIS, (C) AREA POSTREMA SYNDROME, (D) ACUTE BRAINSTEM SYNDROME, (E) SYMPTOMATIC NARCOLEPSY OR ACUTE DIENCEPHALIC CLINICAL SYNDROME WITH NMOSD-TYPICAL DIENCEPHALIC MRI LESIONS, OR (F) SYMPTOMATIC CEREBRAL SYNDROME WITH NMOSD-TYPICAL BRAIN LESIONS, AND 2) NO CONCURRENT USE WITH RITUXIMAB, INEBILIZUMAB, OR ECULIZUMAB. RENEWAL: 1) REDUCTION IN RELAPSE FREQUENCY FROM BASELINE, AND 2) NO CONCURRENT USE WITH RITUXIMAB, OR ECULIZUMAB. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SEBELIPASE ALFA

Products Affected

KANUMA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY: INITIAL: DIAGNOSIS CONFIRMED BY 1) PRESENCE OF CLINICAL FEATURES (E.G., HEPATOMEGALY, ELEVATED SERUM TRANSAMINASES, DYSLIPIDEMIA, SPLENOMEGALY), AND 2) ONE OF THE FOLLOWING: (A) BLOOD TEST INDICATING LOW OR ABSENT LEVELS OF LAL ENZYME ACTIVITY, (B) DRIED BLOOD SPOT TEST INDICATING LOW OR ABSENT LAL ENZYME ACTIVITY, OR (C) GENETIC TEST INDICATING THE BI-ALLELIC PRESENCE OF ALTERED LIPA GENE(S). |
| Age Restrictions | |
| Prescriber Restrictions | LAL DEFICIENCY: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, HEPATOLOGIST, GASTROENTEROLOGIST, MEDICAL GENETICIST, LIPIDOLOGIST, OR METABOLIC SPECIALIST. |
| Coverage Duration | LAL DEFICIENCY: INITIAL: 6 OR 12 MONTHS, SEE OTHER CRITERIA. RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | LAL DEFICIENCY: INITIAL: RAPIDLY PROGRESSIVE LAL DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE: 12 MONTHS. LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: 6 MONTHS. RENEWAL: LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: IMPROVEMENT IN ONE OF THE FOLLOWING CLINICAL PARAMETERS DURING THE PAST 6 MONTHS: (1) A RELATIVE REDUCTION FROM BASELINE IN LDL-C, NON-HDL-C, OR TRIGLYCERIDES, (2) NORMALIZATION OF ASPARTATE AMINOTRANSFERASE (AST) BASED ON AGE- AND GENDER-SPECIFIC NORMAL RANGES, OR (3) DECREASE IN LIVER FAT CONTENT COMPARED TO BASELINE ASSESSED BY ABDOMINAL IMAGING. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SECUKINUMAB

Products Affected

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

• COSENTYX UNOREADY PEN

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI). |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR A DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA, ENTHESITIS-RELATED ARTHRITIS (ERA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG). AS, NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG). ERA: TRIAL OF OR CONTRAINDICATION TO ONE NSAID, SULFASALAZINE, OR METHOTREXATE. RENEWAL: PSO, PSA, AS, NR-AXSPA, ERA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SELEXIPAG

Products Affected

- UPTRAVI INTRAVENOUS
- UPTRAVI ORAL TABLET 1,000 MCG, 1,200 MCG, 1,400 MCG, 1,600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI ORAL TABLETS, DOSE PACK

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | PAH: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS IMPROVED OR REMAINED STABLE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

SELINEXOR

Products Affected

XPOVIO ORAL TABLET 100
 MG/WEEK (50 MG X 2), 40 MG/WEEK
 (40 MG X 1), 40MG TWICE WEEK (40
 MG X 2), 60 MG/WEEK (60 MG X 1),
 60MG TWICE WEEK (120 MG/WEEK),
 80 MG/WEEK (40 MG X 2), 80MG
 TWICE WEEK (160 MG/WEEK)

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SELPERCATINIB

Products Affected

• RETEVMO ORAL CAPSULE 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SELUMETINIB

Products Affected

• KOSELUGO ORAL CAPSULE 10 MG, 25 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SILDENAFIL TABLET

Products Affected

• sildenafil (pulm.hypertension) oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: AGES 18 YEARS OR OLDER: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. AGES 1 TO 17 YEARS: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PAP GREATER THAN 20 MMHG, 2) PCWP OF 15 MMHG OR LESS, AND 3) PVR OF 3 WOOD UNITS OR GREATER. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | PAH: INITIAL: NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS AND 2) AGES 18 YEARS OR OLDER: (A) IMPROVEMENT FROM BASELINE IN THE 6- MINUTE WALK DISTANCE TEST, OR (B) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. AGES 1 TO 17 YEARS: (A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, (B) REMAINS STABLE FROM BASELINE IN THE 6- MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED, OR (C) PHYSICIAN INDICATED THE PATIENT CANNOT PERFORM EXERCISE TESTING AND IS STABLE OR IMPROVING ON TREATMENT. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SIPONIMOD

Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1
 MG, 2 MG
 MAYZENT STARTER(FOR 2MG MAINT)
- MAYZENT STARTER(FOR 1MG MAINT)

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | MULTIPLE SCLEROSIS: RENEWAL: 1) DEMONSTRATION OF CLINICAL BENEFIT COMPARED TO PRE-TREATMENT BASELINE AND 2) DOES NOT HAVE LYMPHOPENIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SIROLIMUS PROTEIN-BOUND

Products Affected

FYARRO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SODIUM OXYBATE

Products Affected

• sodium oxybate

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: 1) NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT, 2) FOR PATIENTS 18 YEARS OR OLDER: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, OR SOLRIAMFETOL AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, AND 3) FOR PATIENTS 7 TO 17 YEARS OF AGE: TRIAL OF OR CONTRAINDICATION TO ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. CATAPLEXY IN NARCOLEPSY: NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT. RENEWAL (ALL INDICATIONS): 1) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE, AND 2) NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

SODIUM PHENYLBUTYRATE TABLETS

Products Affected

• sodium phenylbutyrate oral tablet

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | UREA CYCLE DISORDER (UCD): INITIAL: UCD IS CONFIRMED VIA ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | UCD: RENEWAL: CLINICAL BENEFIT FROM BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOFOSBUVIR/VELPATASVIR

Products Affected

- EPCLUSA ORAL PELLETS IN PACKET 150-37.5 MG, 200-50 MG
- EPCLUSA ORAL TABLET

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, HIV REGIMEN THAT CONTAINS EFAVIRENZ, ROSUVASTATIN AT DOSES ABOVE 10MG, TIPRANAVIR/RITONAVIR, TOPOTECAN, SOVALDI (AS A SINGLE AGENT), HARVONI, ZEPATIER, MAVYRET, OR VOSEVI, AND 3) PATIENTS WITH DECOMPENSATED CIRRHOSIS REQUIRE CONCURRENT RIBAVIRIN UNLESS RIBAVIRIN INELIGIBLE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Products Affected

VOSEVI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) 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 3) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

SOLRIAMFETOL

Products Affected

• SUNOSI

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: EDS IN NARCOLEPSY: TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL, AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. EDS IN OBSTRUCTIVE SLEEP APNEA (OSA): TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL. RENEWAL: EDS IN NARCOLEPSY OR OSA: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOMATROPIN - NORDITROPIN

Products Affected

NORDITROPIN FLEXPRO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING 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 Restrictions | |
| Prescriber Restrictions | INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|--|
| 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 PREPUBERTALGROWTH. 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOMATROPIN - SEROSTIM

Products Affected

 SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI- AGING PURPOSES |
| Required Medical Information | INITIAL: HIV/WASTING: MEETS ONE OF THE FOLLOWING CRITERIA FOR WEIGHT LOSS: 1) 10% UNINTENTIONAL WEIGHT LOSS OVER 12 MONTHS, 2) 7.5% UNINTENTIONAL WEIGHT LOSS OVER 6 MONTHS, 3) 5% BODY CELL MASS (BCM) LOSS WITHIN 6 MONTHS, 4) BODY CELL MASS (BCM) LESS THAN 35% (MEN) OF TOTAL BODY WEIGHT AND BODY MASS INDEX (BMI) LESS THAN 27 KG PER METER SQUARED, 5) BCM LESS THAN 23% (WOMEN) OF TOTAL BODY WEIGHT AND A BODY MASS INDEX (BMI) LESS THAN 27 KG PER METER SQUARED, OR 6) BMI LESS THAN 18.5 KG PER METER SQUARED. |
| Age Restrictions | |
| Prescriber Restrictions | HIV/WASTING: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, NUTRITIONAL SUPPORT SPECIALIST, OR INFECTIOUS DISEASE SPECIALIST. |
| Coverage Duration | INITIAL/RENEWAL: 3 MONTHS. |
| Other Criteria | HIV/WASTING: INITIAL: 1) CURRENTLY ON HIV ANTIRETROVIRAL THERAPY, AND 2) INADEQUATE RESPONSE TO ONE PREVIOUS THERAPY (E.G., MEGACE, APPETITE STIMULANTS, ANABOLIC STEROIDS). RENEWAL: 1) CURRENTLY ON HIV ANTIRETROVIRAL THERAPY, AND 2) CLINICAL BENEFIT IN MUSCLE MASS AND WEIGHT. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

SONIDEGIB

Products Affected

· ODOMZO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | LOCALLY ADVANCED BASAL CELL CARCINOMA (BCC): BASELINE SERUM CREATINE KINASE (CK) AND SERUM CREATININE LEVELS |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SORAFENIB

Products Affected

• sorafenib

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOTORASIB

Products Affected

• LUMAKRAS ORAL TABLET 120 MG, 320 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

STIRIPENTOL

Products Affected

- DIACOMIT ORAL CAPSULE 250 MG, 500 MG
- DIACOMIT ORAL POWDER IN PACKET 250 MG, 500 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | DRAVET SYNDROME: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SUNITINIB

Products Affected

• sunitinib malate

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | GASTROINTESTINAL STROMAL TUMORS (GIST): TRIAL OF OR CONTRAINDICATION TO IMATINIB (GLEEVEC). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TADALAFIL

Products Affected

• tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | ERECTILE DYSFUNCTION WITHOUT DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH). |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | BPH: 1) TRIAL OF ONE ALPHA BLOCKER (E.G., DOXAZOSIN, TERAZOSIN, TAMSULOSIN, ALFUZOSIN), AND 2) TRIAL OF ONE 5-ALPHA-REDUCTASE INHIBITOR (E.G., FINASTERIDE, DUTASTERIDE). APPLIES TO 2.5MG AND 5MG STRENGTHS ONLY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TADALAFIL - ADCIRCA, ALYQ

Products Affected

- alyq
- tadalafil (pulm. hypertension)

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: INITIAL: NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) (A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR (B) REMAINS STABLE FROM BASELINE IN THE 6- MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS REMAINED STABLE OR IMPROVED. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TALAZOPARIB

Products Affected

TALZENNA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: PATIENT HAS BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING. PATIENTS WITH HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER MUST HAVE ADDITIONAL PRIOR TREATMENT WITH ENDOCRINE THERAPY OR BE CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TALIMOGENE

Products Affected

• IMLYGIC INJECTION SUSPENSION 10EXP6 (1 MILLION) PFU/ML

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNRESECTABLE MELANOMA: 1) IMLYGIC TO BE INJECTED INTO CUTANEOUS, SUBCUTANEOUS, AND/OR NODAL LESIONS THAT ARE VISIBLE, PALPABLE, OR DETECTABLE BY ULTRASOUND GUIDANCE, 2) NOT CURRENTLY RECEIVING IMMUNOSUPPRESSIVE THERAPY, 3) NO HISTORY OF PRIMARY OR ACQUIRED IMMUNODEFICIENT STATES, LEUKEMIA, LYMPHOMA, OR AIDS, AND 4) NO CONCURRENT USE WITH PEMBROLIZUMAB, NIVOLUMAB, IPILIMUMAB, DABRAFENIB, TRAMETINIB, VEMURAFENIB, INTERLEUKIN-2, INTERFERON, DACARBAZINE, TEMOZOLOMIDE, PACLITAXEL, CARBOPLATIN, IMATINIB, MELPHALAN, IMIQUIMOD, OR RADIATION THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TALQUETAMAB-TGVS

Products Affected

TALVEY

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TASIMELTEON

Products Affected

- HETLIOZ LQtasimelteon

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | LIFETIME |
| Other Criteria | NON-24 HOUR SLEEP-WAKE DISORDER: PATIENT IS LIGHT-INSENSITIVE OR HAS TOTAL BLINDNESS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAZEMETOSTAT

Products Affected

TAZVERIK

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TBO-FILGRASTIM

Products Affected

• GRANIX

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | NON-MYELOID MALIGNANCIES: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON-MYELOID MALIGNANCIES: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: NIVESTYM. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEBENTAFUSP-TEBN

Products Affected

KIMMTRAK

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TECLISTAMAB-CQYV

Products Affected

TECVAYLI

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEDUGLUTIDE

Products Affected

• GATTEX 30-VIAL

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | SHORT BOWEL SYNDROME (SBS): INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS |
| Other Criteria | SBS: INITIAL: PATIENT IS DEPENDENT ON INTRAVENOUS PARENTERAL NUTRITION DEFINED AS REQUIRING PARENTERAL NUTRITION AT LEAST THREE TIMES PER WEEK. RENEWAL: ACHIEVED OR MAINTAINED A DECREASED NEED FOR PARENTERAL SUPPORT COMPARED TO BASELINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TELOTRISTAT

Products Affected

XERMELO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | CARCINOID SYNDROME DIARRHEA: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST OR GASTROENTEROLOGIST |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEPOTINIB

Products Affected

TEPMETKO

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEPROTUMUMAB-TRBW

Products Affected

TEPEZZA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TERIFLUNOMIDE

Products Affected

• teriflunomide

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TESAMORELIN

Products Affected

• EGRIFTA SV

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 3 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TESTOSTERONE

Products Affected

- testosterone transdermal gel in metereddose pump 12.5 mgl 1.25 gram (1%), 20.25 • mgl1.25 gram (1.62%)
- testosterone transdermal gel in packet 1 %
- (25 mg/2.5gram), 1 % (50 mg/5 gram) testosterone transdermal solution in metered pump w/app

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TESTOSTERONE CYPIONATE

Products Affected

• testosterone cypionate

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TESTOSTERONE ENANTHATE

Products Affected

- testosterone enanthate
- XYOSTED

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | MALE HYPOGONADISM: INITIAL/RENEWAL: 12 MO. ALL OTHER INDICATIONS: LIFETIME OF MEMBERSHIP IN PLAN. |
| Other Criteria | MALE HYPOGONADISM: INITIAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TETRABENAZINE

Products Affected

• tetrabenazine

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HUNTINGTONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEZACAFTOR/IVACAFTOR

Products Affected

SYMDEKO

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: LIFETIME |
| Other Criteria | CF: RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

THALIDOMIDE

Products Affected

• THALOMID

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TILDRAKIZUMAB-ASMN

Products Affected

• ILUMYA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | PSO: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TISOTUMAB VEDOTIN-TFTV

Products Affected

TIVDAK

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TIVOZANIB

Products Affected

FOTIVDA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOCILIZUMAB IV

Products Affected

ACTEMRA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS. |
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). RENEWAL: RA, PJIA, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

TOCILIZUMAB SQ

- ACTEMRA
- ACTEMRA ACTPEN

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|--|
| Other Criteria | INITIAL: RA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). SSC-ILD: DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS). RENEWAL: RA, PJIA, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. SSC-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOFACITINIB

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS (PCJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE- MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PSA, PCJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE. RENEWAL: RA, PSA, AS, PCJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOLVAPTAN

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLETS, SEQUENTIAL

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): INITIAL: 1) CONFIRMED POLYCYSTIC KIDNEY DISEASE VIA CT, MRI, OR ULTRASOUND, AND 2) GENETIC TESTING FOR CAUSATIVE MUTATIONS OR FAMILY HISTORY OF CONFIRMED POLYCYSTIC KIDNEY DISEASE IN ONE OR BOTH PARENTS. |
| Age Restrictions | |
| Prescriber Restrictions | ADPKD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | ADPKD: INITIAL: DOES NOT HAVE ESRD (I.E., RECEIVING DIALYSIS OR HAS UNDERGONE RENAL TRANSPLANT). RENEWAL: HAS NOT PROGRESSED TO ESRD/DIALYSIS OR TRANSPLANT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOPICAL TRETINOIN

- ALTRENO
- tretinoin

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | COSMETIC INDICATIONS SUCH AS WRINKLES, PHOTOAGING, MELASMA. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ACNE VULGARIS: BRAND TOPICAL TRETINOIN REQUIRES TRIAL OF OR CONTRAINDICATION TO A GENERIC TOPICAL TRETINOIN PRODUCT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRAMETINIB

Products Affected

 MEKINIST ORAL TABLET 0.5 MG, 2 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRAMETINIB SOLUTION

Products Affected

• MEKINIST ORAL RECON SOLN

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNABLE TO SWALLOW MEKINIST TABLETS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB HYALURONIDASE

Products Affected

HERCEPTIN HYLECTA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB-ANNS

Products Affected

KANJINTI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB-DKST

Products Affected

• OGIVRI

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB-DTTB

Products Affected

ONTRUZANT

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB-PKRB

Products Affected

• HERZUMA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRASTUZUMAB-QYYP

Products Affected

TRAZIMERA

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TREMELIMUMAB-ACTL

Products Affected

• IMJUDO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | UHCC: 30 DAYS. METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC): 5 MONTHS. |
| Other Criteria | UNRESECTABLE HEPATOCELLULAR CARCINOMA (UHCC): HAS NOT RECEIVED PRIOR TREATMENT WITH IMJUDO. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TREPROSTINIL INHALED

Products Affected

TYVASO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH), PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL: PAH: 12 MONTHS, PH-ILD: 6 MONTHS. RENEWAL: PAH, PH-ILD: 12 MONTHS. |

| PA Criteria | Criteria Details |
|------------------------|--|
| Other Criteria | INITIAL: PAH: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR, 4) FORMULARY VERSION OF AN IV/SQ PROSTACYCLIN. RENEWAL: PAH: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS IMPROVED OR REMAINED STABLE. PH-ILD: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) A STABLE 6-MINUTE WALK DISTANCE TEST. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TREPROSTINIL INJECTABLE

Products Affected

• treprostinil sodium

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|------------------------|---|
| Other Criteria | PAH: INITIAL: 1) CONTINUATION OF THERAPY FROM HOSPITAL DISCHARGE, 2) NEW START AND PHYSICIAN INDICATED PATIENT IS INTERMEDIATE OR HIGH RISK, OR 3) NEW START AND TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: (A) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, (B) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR (C) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINS STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FUNCTIONAL CLASS HAS IMPROVED OR REMAINED STABLE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRIENTINE

Products Affected

• trientine oral capsule 250 mg

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | WILSONS DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 12 MONTHS, RENEWAL: LIFETIME. |
| Other Criteria | WILSONS DISEASE: INITIAL: 1) LEIPZIG SCORE OF 4 OR GREATER, AND 2) TRIAL OF OR CONTRAINDICATION TO FORMULARY VERSION OF PENICILLAMINE TABLET. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRIFLURIDINE/TIPIRACIL

Products Affected

 LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRIPTORELIN-TRELSTAR

Products Affected

 TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS. |
| Other Criteria | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRIPTORELIN-TRIPTODUR

Products Affected

TRIPTODUR

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

TUCATINIB

Products Affected

• TUKYSA ORAL TABLET 150 MG, 50 MG

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

UBROGEPANT

Products Affected

• UBRELVY

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | ACUTE MIGRAINE TREATMENT: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN). RENEWAL: 1) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR 2) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

USTEKINUMAB

Products Affected

• STELARA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

USTEKINUMAB IV

Products Affected

• STELARA

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | 2 MONTHS |
| Other Criteria | CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPURINE, METHOTREXATE, OR MESALAMINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VALBENAZINE

Products Affected

- INGREZZA
- INGREZZA INITIATION PACK

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | TARDIVE DYSKINESIA (TD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | TD: 1) PRIOR HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: AUSTEDO. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VANDETANIB

Products Affected

• CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CURRENTLY STABLE ON CAPRELSA REQUIRES NO EXTRA CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VEMURAFENIB

Products Affected

• ZELBORAF

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | MELANOMA: ZELBORAF WILL BE USED ALONE OR IN COMBINATION WITH COTELLIC |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VENETOCLAX

Products Affected

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

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VERICIGUAT

Products Affected

• VERQUVO

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL:12 MONTHS. |
| Other Criteria | HEART FAILURE (HF): INITIAL: TRIAL OF OR CONTRAINDICATION TO 1) ONE AGENT FROM ANY OF THE FOLLOWING STANDARD OF CARE CLASSES: A) ACE INHIBITOR, ARB, OR ARNI, B) BETA BLOCKER (I.E., BISOPROLOL, CARVEDILOL, METOPROLOL SUCCINATE), OR C) ALDOSTERONE ANTAGONIST (I.E., SPIRONOLACTONE, EPLERENONE), AND 2) ONE PREFERRED SGLT-2 INHIBITOR (E.G., FARXIGA, XIGDUO XR, JARDIANCE). INITIAL/RENEWAL: NOT CONCURRENTLY TAKING LONG-ACTING NITRATES OR NITRIC OXIDE DONORS, RIOCIGUAT, OR PDE-5 INHIBITORS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VESTRONIDASE ALFA VJBK

Products Affected

MEPSEVII

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | MUCOPOLYSACCHARIDOSIS VII (MPS VII): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN GENETIC OR METABOLIC DISORDERS. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | MPS VII: INITIAL: 1) HAS NOT UNDERGONE SUCCESSFUL BONE MARROW OR STEM CELL TREATMENT FOR MPS VII, 2) LIMITATION IN MOBILITY, BUT REMAINS SUFFICIENTLY AMBULATORY, AND 3) DIAGNOSIS CONFIRMED BY: (A) URINARY GAG (GLYCOSAMINOGLYCAN) LEVEL IS GREATER THAN THREE TIMES THE UPPER LEVEL OF NORMAL BASED ON THE LABORATORY ASSAY, (B) BETA-GLUCURONIDASE ENZYME ACTIVITY DEFICIENCY OR GENETIC TESTING, AND (C) ONE OF THE FOLLOWING CLINICAL SIGNS OF MPS VII: ENLARGED LIVER AND SPLEEN, JOINT LIMITATIONS, AIRWAY OBSTRUCTIONS OR PULMONARY DYSFUNCTION. RENEWAL: IMPROVED, MAINTAINED, OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY FROM BASELINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| | <u> </u> |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off Label Uses | |
| Part B Prerequisite | No |

VIGABATRIN

Products Affected

- vigabatrin vigadrone

| PA Criteria | Criteria Details |
|---------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | REFRACTORY COMPLEX PARTIAL SEIZURES (CPS), INFANTILE SPASMS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CPS: TRIAL OF OR CONTRAINDICATION TO TWO ANTIEPILEPTIC AGENTS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VISMODEGIB

Products Affected

• ERIVEDGE

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VORICONAZOLE SUSPENSION

Products Affected

• voriconazole oral suspension for reconstitution

| PA Criteria | Criteria Details |
|---------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CANDIDA INFECTIONS: 3 MOS. ALL OTHER INDICATIONS: 6 MOS. |
| Other Criteria | CANDIDA INFECTIONS: TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE. ALL INDICATIONS: INABILITY TO SWALLOW TABLETS OR AN INDICATION FOR ESOPHAGEAL CANDIDIASIS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZANUBRUTINIB

Products Affected

• BRUKINSA

| PA Criteria | Criteria Details |
|---------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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| VUMERITY9 | 7 |
| WELIREG4 | 2 |
| XADAGO34 | 3 |
| XALKORI7 | 6 |
| XELJANZ40 | 6 |
| XELJANZ XR | 6 |
| XERMELO38 | 8 |
| XGEVA9 | 2 |
| XIFAXAN ORAL TABLET 200 MG, | |
| 550 MG32 | 8 |
| XOLAIR27 | 7 |
| XOSPATA15 | |
| XPOVIO ORAL TABLET 100 | |
| MG/WEEK (50 MG X 2), 40 | |
| MG/WEEK (40 MG X 1), 40MG | |
| TWICE WEEK (40 MG X 2), 60 | |
| MG/WEEK (60 MG X 1), 60MG | |
| TWICE WEEK (120 MG/WEEK), 80 | |
| MG/WEEK (40 MG X 2), 80MG | |
| TWICE WEEK (160 MG/WEEK) 35 | 3 |
| XTANDI ORAL CAPSULE12 | 2 |
| XTANDI ORAL TABLET 40 MG, 80 | |
| MG12 | 2 |
| XYOSTED | 5 |
| YERVOY20 | 8 |
| YONSA | 7 |
| ZARXIO14 | 1 |
| <i>zebutal</i> 17 | 0 |
| ZEJULA ORAL CAPSULE26 | 4 |
| ZEJULA ORAL TABLET26 | 4 |
| ZELBORAF43 | 5 |
| ZIEXTENZO29 | 5 |
| ZIRABEV4 | 9 |
| ZOLADEX16 | 2 |
| ZTALMY15 | 0 |
| ZTLIDO23 | 1 |
| ZYDELIG19 | 3 |
| ZYKADIA6 | 7 |
| ZYNLONTA23 | 6 |