

ABALOPARATIDE

Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | POSTMENOPAUSAL OSTEOPOROSIS: ONE OF THE FOLLOWING: (1) HIGH RISK FOR FRACTURES DEFINED AS ONE OF THE FOLLOWING: A) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S), B) 2 OR MORE RISK FACTORS FOR FRACTURE (E.G., HISTORY OF MULTIPLE RECENT LOW TRAUMA FRACTURES, BMD T-SCORE LESS THAN OR EQUAL TO -2.5, CORTICOSTEROID USE, OR USE OF GNRH ANALOGS), OR C) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR OF AT LEAST 3% FOR HIP FRACTURE, (2) UNABLE TO USE ORAL THERAPY (I.E., UPPER GASTROINTESTINAL PROBLEMS UNABLE TO TOLERATE ORAL MEDICATION, LOWER GASTROINTESTINAL PROBLEMS UNABLE TO ABSORB ORAL MEDICATIONS, TROUBLE REMEMBERING TO TAKE ORAL MEDICATIONS OR COORDINATING AN ORAL BISPHOSPHONATE WITH OTHER ORAL MEDICATIONS OR THEIR DAILY ROUTINE), (3) TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO ONE BISPHOSPHONATE. PATIENT HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

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: ONE OF THE FOLLOWING: 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. |
| 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: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ATNF 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. |
| 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 | ADVANCED OR METASTATIC BREAST CANCER: HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY. |
| 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, METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: ONE OF THE FOLLOWING: 1) PREVIOUSLY 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: ONE OF THE FOLLOWING: 1) PREVIOUSLY 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
- CALQUENCE (ACALABRUTINIB MAL)

| 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 AN OPHTHALMOLOGIST. |
| 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 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 |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p> 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, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, PJA, PSA, AS, PSO, HIDRADENITIS SUPPURATIVA, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION. </p> |
| 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 |

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 X 1), 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: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| 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: PATIENT DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE, OR 2) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. |
| 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 |

APALUTAMIDE

Products Affected

- ERLEADA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): TRIAL OF OR CONTRAINDICATION TO XTANDI OR ABIRATERONE. NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): (1) HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS), AND (2) TRIAL OF OR CONTRAINDICATION TO XTANDI OR NUBEQA. 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 GONADOTROPIN RELEASING HORMONE ANALOG. RENEWAL: DIAGNOSIS OF NMCRPC OR MCSPC. |
| 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 KYNMOBI. |
| 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 | <p>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.</p> |
| Age Restrictions | |
| Prescriber Restrictions | <p>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.</p> |
| Coverage Duration | <p>INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.</p> |
| Other Criteria | <p>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) PATIENT 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,</p> |

| | |
|----------------------------|---|
| PA Criteria | Criteria Details |
| | 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

| 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. |
| 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) |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>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) 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.</p> |
| 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 | EPISODIC 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 | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| 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

Products Affected

- 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

Products Affected

- 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

Products Affected

- 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. |
| Other Criteria | ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY-TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 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, AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. RENEWAL: 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 |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (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. |
| 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-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

Products Affected

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

| 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

Products Affected

- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| 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, 2) AGES 3 TO 17 YEARS OF AGE: A) DEMONSTRATED IMPROVEMENT IN PVR, OR B) REMAINED STABLE OR SHOWN IMPROVEMENT IN EXERCISE ABILITY, 3) AGES 18 YEARS OR OLDER: A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE, OR B) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

| PA Criteria | Criteria Details |
|--------------------------------|-------------------------|
| 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

Products Affected

- 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 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. 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 |

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, 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 THE PRESENCE OF ELEVATED METHYLCITRIC ACID AND NORMAL METHYLMALONIC ACID, OR 2) GENETIC TESTING CONFIRMING MUTATION IN THE PCCA OR PCCB GENE. ACUTE HA DUE TO METHYLMALONIC ACIDEMIA (MMA): 1) CONFIRMED BY THE PRESENCE OF ELEVATED METHYLMALONIC ACID, METHYLCITRIC ACID, OR 2) GENETIC TESTING CONFIRMING 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 |

CERTOLIZUMAB PEGOL

Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST

| 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. 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: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RA: ONE OF THE FOLLOWING: 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, |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: COSENTYX. PATIENTS WHO ARE PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT ARE EXCLUDED FROM STEP CRITERIA FOR ALL INDICATIONS. RENEWAL: RA, PSA, AS, PSO, NR-AXSPA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| 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

Products Affected

- 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 | MS: INITIAL: HAS NOT RECEIVED A TOTAL OF TWO YEARS OF MAVENCLAD TREATMENT (I.E., TWO YEARLY TREATMENT COURSES OF 2 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 2 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) PATIENT IS UNABLE TO TAKE TABLETS OR SUSPENSION, AND 2) TRIAL OF OR CONTRAINDICATION TO A FORMULARY CLOBAZAM AGENT. |
| 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 MA-PD PLAN. |
| 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

- 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

| 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 |

DACOMITINIB

Products Affected

- VIZIMPRO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC 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 |

DAROLUTAMIDE

Products Affected

- NUBEQA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL AND RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): PATIENT HAS HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS) AND ONE OF THE FOLLOWING: 1) PREVIOUSLY 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. METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (MHSPC): 1) PREVIOUSLY 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: NO ADDITONAL CRITERIA REQUIRED. MHSPC: 1) PREVIOUSLY 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 | |

| PA Criteria | Criteria Details |
|--------------------------------|-------------------------|
| 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 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. |
| 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 | |
| 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 ONE OF THE FOLLOWING: 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. RENEWAL (ALL INDICATIONS): SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). |
| 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

| 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: PATIENT HAS A 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(dr/ec) 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 | PA Criteria: Pending CMS Approval |
| Required Medical Information | PA Criteria: Pending CMS Approval |
| Age Restrictions | PA Criteria: Pending CMS Approval |
| Prescriber Restrictions | PA Criteria: Pending CMS Approval |
| Coverage Duration | PA Criteria: Pending CMS Approval |
| Other Criteria | PA Criteria: Pending CMS Approval |
| Indications | PA Criteria: Pending CMS Approval |
| Off Label Uses | PA Criteria: Pending CMS Approval |
| 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 |

ELAGOLIX SODIUM

Products Affected

- ORLISSA 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 | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: 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 A NSAID AND 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 | |
| Part B Prerequisite | No |

ELEXACAFITOR-TEZACAFITOR-IVACAFITOR

Products Affected

- TRIKAFTA

| 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 |

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. |
| 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. |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------|
| 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: PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 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. RENEWAL: DIAGNOSIS OF CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR MCSPC. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EPOETIN ALFA-EPBX

Products Affected

- RETACRIT INJECTION SOLUTION 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML
10,000 UNIT/ML, 2,000 UNIT/ML,
20,000 UNIT/2 ML, 20,000 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: CKD: 1) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR 2) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND DOSE REDUCTION/INTERRUPTION IS REQUIRED TO REDUCE 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. |
| 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. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. |
| 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. |
| 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. |

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

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic) oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *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 | ADVANCED RENAL CELL CARCINOMA (RCC): TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF SUNITINIB OR SORAFENIB. |
| 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 |

FINERENONE

Products Affected

- KERENDIA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES: TRIAL OF OR CONTRAINDICATION TO A SGLT2 INHIBITOR (E.G., FARXIGA, INVOKANA). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINGOLIMOD

Products Affected

- *fingolimod*
- GILENYA

| 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 0.25MG CAPSULES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FREMANEZUMAB-VFRM

Products Affected

- 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 OF OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION. RENEWAL: 1) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH, OR REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH AJOVY THERAPY, AND 2) NO CONCURRENT USE OF 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 MG/ML, 300 MG/3 ML (100 MG/ML X
- EMGALITY SYRINGE 3)
- SUBCUTANEOUS SYRINGE 120

| 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 OF 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 OF AT LEAST 2 DAYS PER MONTH OR A REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH EMGALITY THERAPY, AND 2) NO CONCURRENT USE OF 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

- IRESSA

| 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 |

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

Products Affected

- COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML
- *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 |

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

Products Affected

- *morphine concentrate oral solution*

| 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 |

HYDROXYUREA

Products Affected

- SIKLOS ORAL TABLET 100 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 |

IBRUTINIB

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

| 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 |

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

Products Affected

- *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 | |
| 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. |
| Other Criteria | INITIAL: RA: ONE OF THE FOLLOWING: 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 THE PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | 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 ALFA-2B

Products Affected

- INTRON A INJECTION RECON SOLN

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | HEPATITIS C: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (E.G. HEPATOLOGIST). |
| Coverage Duration | 6 MONTHS. |
| Other Criteria | HEPATITIS C: 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) TRIAL OF OR CONTRAINDICATION TO PEGINTERFERON ALFA-2A OR PEGINTERFERON ALFA-2B, 3) USED IN COMBINATION WITH RIBAVIRIN UNLESS CONTRAINDICATED AND 4) LIMITED TO TOTAL OF 24 MONTHS OF TREATMENT. FOLLICULAR LYMPHOMA: LIMITED TO TOTAL OF 18 MONTHS OF TREATMENT. ALL OTHER INDICATIONS: LIMITED TO TOTAL OF 1 YEAR OF TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INTERFERON FOR MS-AVONEX

Products Affected

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

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 |

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 |

IXEKIZUMAB

Products Affected

- TALTZ AUTOINJECTOR
- TALTZ SYRINGE

| 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. 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 DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, COSENTYX, STELARA, ENBREL. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL, XELJANZ. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, COSENTYX, XELJANZ. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: COSENTYX. RENEWAL: PSO, PSA, AS, NR-AXSPA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

LANADELUMAB

Products Affected

- TAKHZYRO

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

| 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

Products Affected

- 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

Products Affected

- 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 | GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL. |
| 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*
- REVLIMID ORAL CAPSULE 2.5 MG, 20 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 |

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

Products Affected

- 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 | 4 MONTHS |
| Other Criteria | HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT): THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 28 POST TRANSPLANTATION AND PATIENT IS NOT RECEIVING THE MEDICATION BEYOND 100 DAYS POST TRANSPLANTATION. |
| 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 | INITIAL: 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: CPP: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | PROSTATE CANCER: 12 MONTHS. CPP: INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR BREAST DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR GENITAL DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). RENEWAL: 1) TANNER SCALE STAGING AT INITIAL DIAGNOSIS OF CPP HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) PATIENT HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

| PA Criteria | Criteria Details |
|--------------------------------|-------------------------|
| 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

Products Affected

- 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

Products Affected

- 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. |
| Off Label Uses | |

| PA Criteria | Criteria Details |
|--------------------------------|-------------------------|
| 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: PATIENTS 18 YEARS OR OLDER: ONE OF THE FOLLOWING: 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. PATIENTS 5 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: HAS MAINTAINED OR EXPERIENCED REDUCTION IN ACUTE COMPLICATIONS OF SICKLE CELL DISEASE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE

Products Affected

- *lidocaine hcl mucous membrane solution 4 % (40 mg/ml)*
- *lidocaine topical adhesive patch, medicated 5 %*
- *lidocaine topical ointment*
- 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 |

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 |
| 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). |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------------|
| 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 |

LUMACAFITOR-IVACAFITOR

Products Affected

- 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: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| 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, OR 2) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. |
| 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 |

MEPOLIZUMAB

Products Affected

- 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. |
| 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) 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, AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. NASAL POLYPS: PREVIOUS 90 DAY |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>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 FEV1 FROM PRETREATMENT BASELINE. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE.</p> |
| 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 GLUCOCORTICIDS. 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: PATIENT IS SYMPTOMATIC OR HAS 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) PATIENT HAS DEMONSTRATED 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 |

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. |
| 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) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR BREAST DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR GENITAL DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). RENEWAL: CPP: 1) TANNER SCALE STAGING AT INITIAL |

| | |
|----------------------------|--|
| PA Criteria | Criteria Details |
| | DIAGNOSIS OF CPP 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 THE PREFERRED AGENTS: HUMIRA AND STELARA. RENEWAL: CD: ONE OF THE FOLLOWING: 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 | <p>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.</p> |
| Age Restrictions | |
| Prescriber Restrictions | <p>INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.</p> |
| Coverage Duration | <p>INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL (ALL INDICATIONS): 12 MOS.</p> |
| Other Criteria | <p>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</p> |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>WORSENERD/PROGRESSEB DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILB (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE). RENEWAL: IPF, SSC-ILB, PF-ILB: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIRAPARIB

Products Affected

- ZEJULA

| 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 |

NITISINONE

Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE 20 MG
- 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 Criteria | PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL/RENEWAL: COMPLETE BILIARY OBSTRUCTION. |
| Required Medical Information | PBC: INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE 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 Restrictions | PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION 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: 1) MEDICATION WILL BE USED AS MONOTHERAPY, AND 2) PATIENT HAS COMPLETED TWO OR MORE LINES OF PLATINUM-BASED CHEMOTHERAPY. ADVANCED GERMLINE BRCA-MUTATED OVARIAN CANCER AFTER 3 OR MORE LINES OF CHEMOTHERAPY: 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 |

OMACETAXINE

Products Affected

- SYNRIPO

| 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 IDIOPATHIC URTICARIA (CIU): 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: 12 MO. CIU, NASAL POLYPS: 6 MO. RENEWAL: ASTHMA, NASAL POLYPS: 12 MO. CIU: 6 MO. |
| Other Criteria | INITIAL: CIU: TRIAL OF OR CONTRAINDICATION TO A MAXIMALLY TOLERATED DOSE OF AN H1 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 |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>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 OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA.</p> <p>RENEWAL: CIU: DIAGNOSIS OF CIU. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE. ASTHMA: 1) NOT CONCURRENTLY RECEIVING 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 FEV1 FROM PRETREATMENT BASELINE.</p> |
| 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 |

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: 1) IN COMBINATION WITH FULVESTRANT: PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY, 2) IN COMBINATION WITH AN AROMATASE INHIBITOR: NO ADDITIONAL CRITERIA REQUIRED. |
| 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

Products Affected

- *alyq*
- *sildenafil (pulm.hypertension) oral tablet*
- *tadalafil (pulm. hypertension)*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| 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) 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) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER. 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) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

PEGFILGRASTIM

Products Affected

- NEULASTA

| 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 | NON MYELOID MALIGNANCY: TRIAL OF OR CONTRAINDICATION TO NYVEPRIA. |
| 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

| 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-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 |

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) PATIENT 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 | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: WILSONS DISEASE: CONFIRMED BY ONE OF THE FOLLOWING: 1) PLASMA COPPER-PROTEIN CERULOPLASMIN IS LESS THAN 20MG/DL, 2) LIVER BIOPSY POSITIVE FOR AN ABNORMALLY HIGH CONCENTRATION OF COPPER (GREATER THAN 250MCG/G DRY WEIGHT) OR THE PRESENCE OF KAYSER-FLEISCHER RINGS, OR 3) CONFIRMATION BY GENETIC TESTING FOR ATP7B MUTATIONS. CYSTINURIA: PATIENT HAS NEPHROLITHIASIS AND ONE OR MORE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTEINE, 2) IDENTIFICATION OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) POSITIVE FAMILY HISTORY OF CYSTINURIA WITH POSITIVE CYANIDE-NITROPRUSSIDE SCREEN. |
| Age Restrictions | |
| Prescriber Restrictions | WILSONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST. 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. |
| Other Criteria | INITIAL: WILSONS DISEASE: 1) KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE, AND 2) REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRE A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN). CYSTINURIA: REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRES A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN) AND A FORMULARY VERSION OF TIOPRONIN (THIOLA)/THIOLA EC. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, 2) TRIAL OF OR |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>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, AND 3) REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRES A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN). RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS DISEASE, CYSTINURIA: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p> |
| 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

- ESBRIET ORAL CAPSULE
- *pirfenidone oral tablet 267 mg, 534 mg, 801 mg*

| 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 | |
| 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

- NOXAFIL ORAL SUSPENSION
- *posaconazole*

| 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. POSACONAZOLE TABLETS ONLY: TREATMENT OF INVASIVE ASPERGILLOSIS: NO EXTRA CRITERIA REQUIRED. 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/MM ³ 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 |

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: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| Coverage Duration | ASTHMA: INITIAL 4 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | ASTHMA: INITIAL: 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) 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) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT, AND 4) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. RENEWAL: 1) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>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 FEV1 FROM PRETREATMENT BASELINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIBOCICLIB

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
- 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: 1) REQUIRES A TRIAL OF OR CONTRAINDICATION TO VERZENIO OR IBRANCE WHERE INDICATIONS ALIGN AND 2) PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY. |
| 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 OF 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 OF OTHER CGRP INHIBITORS FOR MIGRAINE PREVENTION, AND 2) REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH OR REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIOCIQUAT

Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4: NYHA-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 AND RENEWAL: 12 MONTHS. |
| 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, OR ANY 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) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS, AND 2) NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------|
| 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 |

RISANKIZUMAB-RZAA

Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PLAQUE 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: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PSO: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE, AND 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG), AND 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA, XELJANZ IR OR XR. CD: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: HUMIRA AND STELARA. RENEWAL: PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------------|
| 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 | PATIENT 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 | INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY 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: RA: 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): 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: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY 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 | INITIAL: RA: 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 | INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY 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: RA: 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 |

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 |

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 | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| Other Criteria | RA: INITIAL: ONE OF THE FOLLOWING: 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 |

SECUKINUMAB

Products Affected

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

| 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 |
| 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. |

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

SELEXIPAG

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS. |
| 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: WHO FC II-III SYMPTOMS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS, EACH FROM A DIFFERENT DRUG CLASS: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIAL RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. WHO FC III SYMPTOMS AND EVIDENCE OF RAPID PROGRESSION OR POOR PROGNOSIS, WHO FC IV SYMPTOMS: NO STEP. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINED STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FC HAS IMPROVED OR REMAINED STABLE. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------|
| Off Label Uses | |
| 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 |

SIPONIMOD

Products Affected

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

SODIUM OXYBATE

Products Affected

- XYREM

| 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 THE FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, PITOLISANT 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 OTHER 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 | |
| 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 | PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL. |
| 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, TIPRANA VIR/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 | PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL. |
| 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. |
| 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. |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------|
| 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. |
| 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

| 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*

| 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 |

TALAZOPARIB

Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | 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. |
| 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 |

TASIMELTEON

Products Affected

- HETLIOZ

| 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 |

TERIFLUNOMIDE

Products Affected

- AUBAGIO

| 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 |

TERIPARATIDE

Products Affected

- FORTEO SUBCUTANEOUS PEN
INJECTOR 20 MCG/DOSE
(600MCG/2.4ML)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | <p>OSTEOPOROSIS: ONE OF THE FOLLOWING: (1) HIGH RISK FOR FRACTURES DEFINED AS ONE OF THE FOLLOWING: A) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S), B) 2 OR MORE RISK FACTORS FOR FRACTURE (E.G., HISTORY OF MULTIPLE RECENT LOW TRAUMA FRACTURES, BMD T-SCORE LESS THAN OR EQUAL TO -2.5, CORTICOSTEROID USE, OR USE OF GNRH ANALOGS SUCH AS NAFARELIN, ETC.), C) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR OF AT LEAST 3% FOR HIP FRACTURE, (2) UNABLE TO USE ORAL THERAPY (I.E., UPPER GASTROINTESTINAL PROBLEMS UNABLE TO TOLERATE ORAL MEDICATION, LOWER GASTROINTESTINAL PROBLEMS UNABLE TO ABSORB ORAL MEDICATIONS, TROUBLE REMEMBERING TO TAKE ORAL MEDICATIONS OR COORDINATING AN ORAL BISPHOSPHONATE WITH OTHER ORAL MEDICATIONS OR THEIR DAILY ROUTINE), (3) TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO ONE BISPHOSPHONATE. PATIENT HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT UNLESS PATIENT REMAINS AT OR HAS RETURNED TO HAVING A HIGH RISK FOR FRACTURE.</p> |

| PA Criteria | Criteria Details |
|----------------------------|-------------------------------|
| 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 cypionate intramuscular oil 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*
- *testosterone enanthate*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 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*
- XYOSTED

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: MALE HYPOGONADISM: CONFIRMED BY: 1) AT LEAST TWO MORNING TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS WHILE IN A FASTED STATE, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 PG/ML. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | MALE HYPOGONADISM: INITIAL/RENEWAL:12 MO. ALL OTHER INDICATIONS: LIFETIME OF MEMBERSHIP IN PLAN. |
| Other Criteria | RENEWAL: MALE HYPOGONADISM: 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 |

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 | |
| 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: ONE OF THE FOLLOWING: 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. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOCILIZUMAB SQ

Products Affected

- 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. |
| Other Criteria | INITIAL: RA: ONE OF THE FOLLOWING: 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: |

| | |
|----------------------------|---|
| PA Criteria | Criteria Details |
| | CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOFACITINIB

Products Affected

- 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, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. RENEWAL: RA, PSA, AS, PCJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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

TOPICAL TRETINOIN

Products Affected

- 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 |

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-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 | 30 DAYS |
| 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 |

TRIENTINE

Products Affected

- *trientine*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | WILSONS DISEASE: INITIAL: KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE. CONFIRMATION OF ONE OF THE FOLLOWING: 1) PLASMA COPPER-PROTEIN CERULOPLASMIN LESS THAN 20 MG/DL, 2) LIVER BIOPSY POSITIVE FOR AN ABNORMALLY HIGH CONCENTRATION OF COPPER (GREATER THAN 250 MCG/G DRY WEIGHT) OR THE PRESENCE OF KAYSER-FLEISCHER RINGS, OR 3) CONFIRMATION BY GENETIC TESTING FOR ATP7B MUTATIONS. |
| 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: TRIAL OF OR CONTRAINDICATION TO FORMULARY VERSION OF PENICILLAMINE (DEPEN). RENEWAL: PATIENT 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 |

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, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| 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, MERCAPTOPYRINE, 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 |

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 |

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: 1) TRIAL OF OR CONTRAINDICATION TO TWO ANTIEPILEPTIC AGENTS AND 2) BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS. INFANTILE SPASMS: BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS. |
| 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 |

INDEX

A

| | |
|--|---------------|
| abiraterone | 6 |
| ACTEMRA | 294, 295, 296 |
| ACTEMRA ACTPEN..... | 295, 296 |
| ACTHAR | 64 |
| ACTIMMUNE..... | 137 |
| ADEMPAS..... | 238, 239 |
| AJOVY AUTOINJECTOR | 113 |
| AJOVY SYRINGE | 113 |
| ALECENSA | 12 |
| ALTRENO | 299 |
| ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG | 47 |
| ALUNBRIG ORAL TABLETS,DOSE PACK..... | 47 |
| alyq | 206, 207 |
| ambrisentan | 14 |
| apomorphine | 17 |
| armodafinil | 180 |
| AUBAGIO | 284 |
| AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG | 77 |
| AVONEX INTRAMUSCULAR PEN INJECTOR KIT | 134 |
| AVONEX INTRAMUSCULAR SYRINGE KIT..... | 134 |
| AYVAKIT..... | 25 |

B

| | |
|---|-----|
| BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG | 98 |
| BENDEKA | 35 |
| BENLYSTA SUBCUTANEOUS | 32 |
| BESREMI..... | 248 |
| betaine | 38 |
| BETASERON SUBCUTANEOUS KIT | 135 |
| bexarotene | 41 |
| bortezomib injection recon soln 1 mg, 2.5 mg | 43 |
| BORTEZOMIB INTRAVENOUS RECON SOLN | 43 |
| BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG | 46 |
| BRAFTOVI ORAL CAPSULE 75 MG ... | 94 |
| BRUKINSA..... | 320 |

C

| | |
|--|----------|
| CABLIVI INJECTION KIT..... | 53 |
| CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG | 51 |
| CALQUENCE..... | 8 |
| CALQUENCE (ACALABRUTINIB MAL) | 8 |
| CAPRELSA ORAL TABLET 100 MG, 300 MG..... | 314 |
| carglumic acid | 55 |
| CAYSTON..... | 29 |
| CERDELGA | 89 |
| CIMZIA | 57, 58 |
| CIMZIA POWDER FOR RECONST. 57, 58 | |
| CINQAIR..... | 233, 234 |
| CINRYZE | 48 |
| colchicine oral tablet..... | 63 |
| 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) | 50 |
| COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML.... | 120 |
| COPIKTRA..... | 86 |
| CORTROPHIN GEL | 64 |
| COSENTYX (2 SYRINGES)..... | 253, 254 |
| COSENTYX PEN (2 PENS)..... | 253, 254 |
| COSENTYX SUBCUTANEOUS SYRINGE 75 MG/0.5 ML | 253, 254 |
| COTELLIC | 62 |
| CYRAMZA..... | 230 |
| CYSTARAN | 66 |

D

| | |
|--|-----|
| dalfampridine | 69 |
| DANYELZA..... | 182 |
| DAURISMO ORAL TABLET 100 MG, 25 MG..... | 119 |
| deferasirox..... | 74 |
| deferiprone | 75 |
| DIACOMIT ORAL CAPSULE 250 MG, 500 MG | 272 |
| DIACOMIT ORAL POWDER IN PACKET 250 MG, 500 MG | 272 |
| diclofenac sodium topical gel 3 % | 78 |

| | |
|--|----------|
| diclofenac sodium topical solution in metered-dose pump | 79 |
| dimethyl fumarate oral capsule, delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg..... | 80 |
| DOPTELET (10 TAB PACK) | 26 |
| DOPTELET (15 TAB PACK) | 26 |
| DOPTELET (30 TAB PACK) | 26 |
| dronabinol..... | 83 |
| droxidopa..... | 84 |
| DUPIXENT PEN | 85 |
| DUPIXENT SYRINGE..... | 85 |
| E | |
| EGRIFTA SV | 287 |
| ELIGARD | 155 |
| ELIGARD (3 MONTH) | 155 |
| ELIGARD (4 MONTH) | 155 |
| ELIGARD (6 MONTH) | 155 |
| EMGALITY PEN | 115 |
| EMGALITY SYRINGE | |
| SUBCUTANEOUS SYRINGE 120 MG/ML, 300 MG/3 ML (100 MG/ML X 3)..... | 115 |
| ENBREL | 101, 102 |
| ENBREL MINI..... | 101, 102 |
| ENBREL SURECLICK | 101, 102 |
| ENDARI..... | 159 |
| EPCLUSA ORAL PELLETS IN PACKET 150-37.5 MG, 200-50 MG..... | 262 |
| EPCLUSA ORAL TABLET | 262 |
| EPIDIOLEX | 52 |
| ERBITUX..... | 59 |
| ERIVEDGE..... | 318 |
| ERLEADA | 16 |
| erlotinib oral tablet 100 mg, 150 mg, 25 mg | 99 |
| ESBRIET ORAL CAPSULE..... | 221 |
| everolimus (antineoplastic) oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg..... | 103 |
| everolimus (antineoplastic) oral tablet for suspension..... | 103 |
| EVRYSDI..... | 243 |
| EXKIVITY | 177 |
| F | |
| FARYDAK..... | 202 |
| FASENRA..... | 36, 37 |

| | |
|--|----------|
| FASENRA PEN | 36, 37 |
| fentanyl citrate buccal lozenge on a handle | 106 |
| FERRIPROX (2 TIMES A DAY) | 75 |
| FERRIPROX ORAL SOLUTION..... | 75 |
| figolimod..... | 111 |
| FINTEPLA..... | 105 |
| FORTEO SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (600MCG/2.4ML)..... | 285, 286 |
| FOTIVDA..... | 293 |
| FULPHILA | 211 |
| G | |
| GALAFOLD | 174 |
| GAMIFANT..... | 91, 92 |
| GATTEX 30-VIAL | 281 |
| GAVRETO..... | 226 |
| GILENYA..... | 111 |
| GILOTRIF | 11 |
| glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml | 120 |
| glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml..... | 120 |
| GRANIX..... | 278 |
| H | |
| HAEGARDA SUBCUTANEOUS RECON SOLN 2,000 UNIT, 3,000 UNIT | 49 |
| HARVONI ORAL PELLETS IN PACKET 33.75-150 MG, 45-200 MG..... | 148 |
| HARVONI ORAL TABLET | 148 |
| HERCEPTIN HYLECTA | 301 |
| HERZUMA..... | 304 |
| HETLIOZ..... | 276 |
| HUMIRA PEN | 9, 10 |
| HUMIRA PEN CROHNS-UC-HS START | 9, 10 |
| HUMIRA PEN PSOR-UEVITS-ADOL HS | 9, 10 |
| HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML | 9, 10 |
| HUMIRA(CF)..... | 9, 10 |
| HUMIRA(CF) PEDI CROHNS STARTER | 9, 10 |
| HUMIRA(CF) PEN | 9, 10 |
| HUMIRA(CF) PEN CROHNS-UC-HS | 9, 10 |
| HUMIRA(CF) PEN PEDIATRIC UC | 9, 10 |

HUMIRA(CF) PEN PSOR-UV-ADOL HS
.....9, 10

I

IBRANCE 201
ibuprofen-famotidine..... 126
icatibant..... 127
ICLUSIG..... 223
IDHIFA..... 93
imatinib oral tablet 100 mg, 400 mg 129
IMBRUVICA ORAL CAPSULE 140 MG,
70 MG 125
IMBRUVICA ORAL SUSPENSION 125
IMBRUVICA ORAL TABLET..... 125
IMJUDO..... 306
IMLYGIC INJECTION SUSPENSION
10EXP6 (1 MILLION) PFU/ML 275
IMPAVIDO..... 176
INBRIJA INHALATION CAPSULE,
W/INHALATION DEVICE 158
infliximab 131, 132
INLYTA ORAL TABLET 1 MG, 5 MG . 27
INQOVI 73
INREBIC..... 104
INTRON A INJECTION RECON SOLN
..... 133
IRESSA..... 117

J

JAKAFI..... 250
javvygtor oral tablet,soluble 251
JEMPERLI 82
JUXTAPID ORAL CAPSULE 10 MG, 20
MG, 30 MG, 40 MG, 5 MG, 60 MG . 162,
163

K

KALYDECO 139
KERENDIA..... 110
KESIMPTA PEN..... 193
KEVZARA 252
KEYTRUDA 215
KIMMTRAK..... 279
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 235

KISQALI ORAL TABLET 200 MG/DAY
(200 MG X 1), 400 MG/DAY (200 MG X
2), 600 MG/DAY (200 MG X 3) 235
KORLYM..... 173
KOSELUGO ORAL CAPSULE 10 MG, 25
MG.....259
KYNMOBI SUBLINGUAL FILM 10 MG,
10-15-20-25-30 MG, 15 MG, 20 MG, 25
MG, 30 MG18

L

lanreotide 145
lapatinib 146
lenalidomide..... 149
LENVIMA 150
leuprolide (3 month) 154
leuprolide subcutaneous kit 152, 153
lidocaine hcl mucous membrane solution 4
% (40 mg/ml)..... 160
lidocaine topical adhesive patch,medicated 5
% 160
lidocaine topical ointment 160
lidocaine-prilocaine topical cream 161
LONSURF ORAL TABLET 15-6.14 MG,
20-8.19 MG 308
LORBRENA ORAL TABLET 100 MG, 25
MG..... 165
LUMAKRAS 271
LUPRON DEPOT 156, 157
LUPRON DEPOT (3 MONTH) 156, 157
LUPRON DEPOT (4 MONTH) 156, 157
LUPRON DEPOT (6 MONTH) 156, 157
LYBALVI..... 194
LYNPARZA 195
LYTGOBI..... 114

M

MARGENZA 169
MAVENCLAD (10 TABLET PACK)..... 60
MAVENCLAD (4 TABLET PACK)..... 60
MAVENCLAD (5 TABLET PACK)..... 60
MAVENCLAD (6 TABLET PACK)..... 60
MAVENCLAD (7 TABLET PACK)..... 60
MAVENCLAD (8 TABLET PACK)..... 60
MAVENCLAD (9 TABLET PACK)..... 60
MAYZENT ORAL TABLET 0.25 MG, 1
MG, 2 MG 260

| | |
|---|----------|
| MAYZENT STARTER(FOR 1MG MAINT) | 260 |
| MAYZENT STARTER(FOR 2MG MAINT) | 260 |
| MEKINIST ORAL TABLET 0.5 MG, 2 MG | 300 |
| MEKTOVI | 42 |
| miglustat | 175 |
| modafinil oral tablet 100 mg, 200 mg | 180 |
| morphine concentrate oral solution | 123 |
| MVASI | 39 |
| N | |
| NATPARA | 203 |
| NERLYNX | 183 |
| NEULASTA | 208 |
| NEULASTA ONPRO | 212 |
| NINLARO | 141 |
| nitisinone | 188 |
| NIVESTYM | 107 |
| NORDITROPIN FLEXP | 266, 267 |
| NOXAFIL ORAL SUSP,DELAYED RELEASE FOR RECON | 225 |
| NOXAFIL ORAL SUSPENSION | 224 |
| NUBEQA | 70, 71 |
| NUCALA SUBCUTANEOUS AUTO-INJECTOR | 170, 171 |
| NUCALA SUBCUTANEOUS RECON SOLN | 170, 171 |
| NUCALA SUBCUTANEOUS SYRINGE 100 MG/ML, 40 MG/0.4 ML | 170, 171 |
| NUPLAZID | 220 |
| NURTEC ODT | 237 |
| NYVEPRIA | 209 |
| O | |
| OCALIVA | 191 |
| OCREVUS | 192 |
| ODOMZO | 269 |
| OFEV | 185, 186 |
| OGIVRI | 302 |
| OLUMIANT | 30 |
| ONTRUZANT | 303 |
| ONUREG | 28 |
| OPDIVO | 189 |
| OPDUALAG | 190 |
| OPSUMIT | 168 |
| ORENCIA | 4 |

| | |
|--|----------|
| ORENCIA (WITH MALTOSE) | 3 |
| ORENCIA CLICKJECT | 4 |
| ORFADIN ORAL CAPSULE 20 MG | 188 |
| ORFADIN ORAL SUSPENSION | 188 |
| ORGOVYX | 232 |
| ORLISSA ORAL TABLET 150 MG, 200 MG | 87 |
| ORKAMBI ORAL GRANULES IN PACKET | 166 |
| ORKAMBI ORAL TABLET | 166 |
| OTEZLA | 19, 20 |
| OTEZLA STARTER | 19, 20 |
| OXLUMO | 167 |
| P | |
| PALYNZIQ | 213 |
| PEMAZYRE | 216 |
| penicillamine oral tablet | 217, 218 |
| 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) | 13 |
| pirfenidone oral tablet 267 mg, 534 mg, 801 mg | 221 |
| PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML | 136 |
| PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML | 136 |
| POMALYST | 222 |
| posaconazole | 224 |
| PREVYMIS INTRAVENOUS SOLUTION 240 MG/12 ML, 480 MG/24 ML | 151 |
| PREVYMIS ORAL | 151 |
| PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG | 90 |
| PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG | 90 |
| pyrimethamine | 228 |
| Q | |
| QINLOCK | 240 |
| quinine sulfate | 229 |
| QULIPTA | 24 |
| R | |
| RAVICTI | 121 |
| RELEUKO | 108 |

| | |
|--|----------|
| 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 | 97 |
| RETEVMO ORAL CAPSULE 40 MG, 80 | |
| MG | 258 |
| REVLIMID ORAL CAPSULE 2.5 MG, 20 | |
| MG | 149 |
| REZUROCK..... | 33 |
| RIABNI..... | 246 |
| RITUXAN HYCELA..... | 244 |
| ROZLYTREK ORAL CAPSULE 100 MG, | |
| 200 MG | 95 |
| RUBRACA..... | 249 |
| RUXIENCE..... | 247 |
| RYBREVANT..... | 15 |
| RYDAPT..... | 172 |
| S | |
| sajazir | 127 |
| sapropterin oral tablet,soluble | 251 |
| SCSEMBLIX..... | 21 |
| SEROSTIM SUBCUTANEOUS RECON | |
| SOLN 4 MG, 5 MG, 6 MG..... | 268 |
| SIGNIFOR | 204 |
| SIKLOS ORAL TABLET 100 MG | 124 |
| sildenafil (pulm.hypertension) oral tablet | |
| | 206, 207 |
| SIRTURO..... | 31 |
| SKYRIZI INTRAVENOUS | 241, 242 |
| SKYRIZI SUBCUTANEOUS WEARABLE | |
| INJECTOR | 241, 242 |
| SOMATULINE DEPOT | |
| SUBCUTANEOUS SYRINGE 120 | |
| MG/0.5 ML, 60 MG/0.2 ML, 90 MG/0.3 | |
| ML | 145 |
| SOMAVERT | 214 |
| sorafenib..... | 270 |
| SPRAVATO..... | 100 |
| SPRYCEL ORAL TABLET 100 MG, 140 | |
| MG, 20 MG, 50 MG, 70 MG, 80 MG .. | 72 |
| STELARA..... | 312, 313 |
| STIVARGA..... | 231 |
| STRENSIQ..... | 22, 23 |
| sunitinib..... | 273 |
| SUNOSI | 265 |
| SYMDEKO..... | 290 |
| SYMLINPEN 120 | 227 |
| SYMLINPEN 60 | 227 |
| SYMPAZAN..... | 61 |
| SYNAREL | 178, 179 |
| SYNRIBO..... | 196 |
| T | |
| TABRECTA..... | 54 |
| tadalafil (pulm. hypertension)..... | 206, 207 |
| TAFINLAR..... | 67 |
| TAGRISO | 199 |
| TAKHZYRO..... | 144 |
| TALTZ AUTOINJECTOR | 142, 143 |
| TALTZ SYRINGE | 142, 143 |
| TALZENNA | 274 |
| TASCENSO ODT | 112 |
| TASIGNA ORAL CAPSULE 150 MG, 200 | |
| MG, 50 MG | 184 |
| TAZVERIK..... | 277 |
| TECVAYLI..... | 280 |
| TEPMETKO | 283 |
| testosterone cypionate intramuscular oil 100 | |
| mg/ml, 200 mg/ml, 200 mg/ml (1 ml) . | 288 |
| testosterone enanthate | 288 |
| testosterone transdermal gel in metered-dose | |
| pump 12.5 mg/ 1.25 gram (1 %), 20.25 | |
| mg/1.25 gram (1.62 %) | 288 |
| testosterone transdermal gel in packet 1 % | |
| (25 mg/2.5gram), 1 % (50 mg/5 gram) | 288 |
| testosterone transdermal solution in metered | |
| pump w/app | 288 |
| tetrabenazine | 289 |
| THALOMID | 291 |
| TIBSOVO | 140 |
| TIVDAK..... | 292 |
| TRACLEER ORAL TABLET | 44, 45 |
| TRACLEER ORAL TABLET FOR | |
| SUSPENSION | 44, 45 |
| TRAZIMERA..... | 305 |
| TRELSTAR INTRAMUSCULAR | |
| SUSPENSION FOR | |
| RECONSTITUTION | 309 |
| tretinoin | 299 |
| trientine | 307 |
| TRIKAFTA..... | 88 |
| TRUSELTIQ..... | 130 |

| | |
|--|----------|
| TRUXIMA | 245 |
| TUKYSA ORAL TABLET 150 MG, 50 MG | 310 |
| TURALIO | 219 |
| TYMLOS | 1, 2 |
| TYSABRI..... | 181 |
| U | |
| UBREL VY | 311 |
| UDENYCA | 210 |
| UPTRAVI INTRAVENOUS..... | 255, 256 |
| UPTRAVI ORAL TABLET 1,000 MCG, 1,200 MCG, 1,400 MCG, 1,600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG..... | 255, 256 |
| UPTRAVI ORAL TABLETS,DOSE PACK | 255, 256 |
| V | |
| VELCADE | 43 |
| VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG..... | 316 |
| VENCLEXTA STARTING PACK..... | 316 |
| VERZENIO | 5 |
| vigabatrin..... | 317 |
| vigadrone..... | 317 |
| VITRAKVI ORAL CAPSULE 100 MG, 25 MG | 147 |
| VITRAKVI ORAL SOLUTION..... | 147 |
| VIZIMPRO..... | 68 |
| VONJO..... | 200 |
| voriconazole oral suspension for reconstitution | 319 |
| VOSEVI..... | 263, 264 |
| VOTRIENT | 205 |
| VUMERITY | 81 |
| W | |
| WELIREG..... | 34 |

| | |
|--|----------|
| X | |
| XALKORI..... | 65 |
| XELJANZ..... | 297, 298 |
| XELJANZ XR..... | 297, 298 |
| XERMELO | 282 |
| XGEVA | 76 |
| XIFAXAN ORAL TABLET 200 MG, 550 MG..... | 236 |
| XOLAIR | 197, 198 |
| XOSPATA | 118 |
| 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)..... | 257 |
| XTANDI ORAL CAPSULE | 96 |
| XTANDI ORAL TABLET 40 MG, 80 MG | 96 |
| XYOSTED..... | 288 |
| XYREM..... | 261 |
| Y | |
| YERVOY | 138 |
| YONSA..... | 7 |
| Z | |
| ZARXIO | 109 |
| ZEJULA..... | 187 |
| ZELBORAF..... | 315 |
| ZIRABEV | 40 |
| ZOLADEX..... | 122 |
| ZTALMY | 116 |
| ZTLIDO | 160 |
| ZYDELIG | 128 |
| ZYKADIA | 56 |
| ZYNLONTA..... | 164 |