

ABALOPARATIDE

Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 24 MONTHS |
| Other Criteria | OSTEOPOROSIS: HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ABATACEPT IV

Products Affected

- ORENCIA INTRAVENOUS

| 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 MOS, RENEWAL: 12 MOS. ACUTE GRAFT VERSUS HOST DISEASE (AGVHD): 1 MO. |
| 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 1): TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

Formulary ID: 25489
 Effective: 01/01/2025
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| PA Criteria | Criteria Details |
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| Part B Prerequisite | No |

ABATACEPT SQ

Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| 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: 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: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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Effective: 01/01/2025
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| Part B Prerequisite | No |

ABEMACICLIB

Products Affected

- VERZENIO

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

ABIRATERONE

Products Affected

- *abiraterone acetate*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC HIGH-RISK CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC), METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ABIRATERONE SUBMICRONIZED

Products Affected

- YONSA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ACALABRUTINIB

Products Affected

- CALQUENCE

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

ADAGRASIB

Products Affected

- KRAZATI

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

ADALIMUMAB

Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS AUTO-INJECTOR KIT 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PED<40KG CROHNS STARTER
- HUMIRA-PED>=40KG CROHNS START
- HUMIRA-PED>=40KG UC STARTER SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA-PS/UV/ADOL HS STARTER SUBCUTANEOUS AUTO-INJECTOR KIT
- HUMIRA-PSORIASIS/UVEIT STARTER SUBCUTANEOUS PEN-INJECTOR KIT

| 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, PJIA, ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST OR RHEUMATOLOGIST. PSO, HIDRADENITIS SUPPURATIVA (HS): PRESCRIBED BY OR IN CONSULTATION WITH DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH OPHTHALMOLOGIST |
| Coverage Duration | INITIAL: RA, PSO, PJIA, AS, PSA, CD, UC, UVEITIS: 6 MONTHS, HS: 3 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RHEUMATOID ARTHRITIS (RA): TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE |

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Effective: 01/01/2025
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|-------------|---|
| | <p>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.</p> <p>POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSO: 1) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. CD, UC: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY (E.G., CORTICOSTEROID [E.G., BUDESONIDE, METHYLPREDNISOLONE], AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, MESALAMINE), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. HS: NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR HS OR TNF INHIBITORS FOR ANY INDICATION. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA, PSA, AS, PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. CD, UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR</p> |

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| PA Criteria | Criteria Details |
| | TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| 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 NON-SMALL CELL LUNG CANCER (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-PIQRAY

Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| 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 |

AMIKACIN LIPOSOMAL INH

Products Affected

- ARIKAYCE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE: RENEWAL: 1) NO POSITIVE MAC SPUTUM CULTURE AFTER CONSECUTIVE NEGATIVE CULTURES, AND 2) IMPROVEMENT IN SYMPTOMS. ADDITIONALLY, FOR FIRST RENEWAL, APPROVAL REQUIRES AT LEAST ONE NEGATIVE SPUTUM CULTURE FOR MAC BY SIX MONTHS OF ARIKAYCE TREATMENT. FOR SECOND AND SUBSEQUENT RENEWALS, APPROVAL REQUIRES AT LEAST THREE NEGATIVE SPUTUM CULTURES FOR MAC BY 12 MONTHS OF ARIKAYCE TREATMENT. |
| Age Restrictions | |
| Prescriber Restrictions | MAC LUNG DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST. |
| Coverage Duration | INITIAL/RENEWAL: 6 MONTHS. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AMIVANTAMAB-VMJW

Products Affected

- RYBREVANT

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

ANAKINRA

Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS. |
| Required Medical Information | INITIAL: CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE IL1RN GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR), AND 2) ONE OF THE FOLLOWING: PUSTULAR PSORIASIS-LIKE RASHES, OSTEOMYELITIS, ABSENCE OF BACTERIAL OSTEOMYELITIS, ONYCHOMADESIS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. CAPS, DIRA: LIFETIME. |
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. CAPS, DIRA: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

Formulary ID: 25489
Effective: 01/01/2025
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| Part B Prerequisite | No |

APALUTAMIDE

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

| PA Criteria | Criteria Details |
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| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC, METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: NMCRPC, MCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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APOMORPHINE - SL

Products Affected

- KYNMOBI
- KYNMOBI TITRATION KIT

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

APREMILAST

Products Affected

- OTEZLA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: MILD PLAQUE PSORIASIS (PSO): 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: PSORIASIS COVERING 3 PERCENT OR MORE OF BSA, OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. BEHCETS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. MILD PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL SYSTEMIC THERAPY (E.G., METHOTREXATE, ACITRETIN, CYCLOSPORINE) OR ONE CONVENTIONAL TOPICAL THERAPY (E.G., PUVA [PHOTOTHERAPY], UVB [ULTRAVIOLET LIGHT B], TOPICAL CORTICOSTEROIDS). MODERATE TO SEVERE PSO: 1) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR |

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| | <p>INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. BEHCETS DISEASE: 1) HAS ORAL ULCERS OR A HISTORY OF RECURRENT ORAL ULCERS BASED ON CLINICAL SYMPTOMS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OR MORE CONSERVATIVE TREATMENTS (E.G., COLCHICINE, TOPICAL CORTICOSTEROID, ORAL CORTICOSTEROID). RENEWAL: MILD PSO, BEHCETS DISEASE: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA, MODERATE TO SEVERE PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ASCIMINIB

Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

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

ASFOTASE ALFA

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 |

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| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALP LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PLP LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PEA LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC DEFORMITIES, (II) PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 YEARS OF AGE, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) 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 | 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 |

AVACOPAN

Products Affected

- TAVNEOS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY (ANCA)-ASSOCIATED VASCULITIS: INITIAL: ANCA SEROPOSITIVE (ANTI-PR3 OR ANTI-MPO). |
| Age Restrictions | |
| Prescriber Restrictions | ANCA-ASSOCIATED VASCULITIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 6 MONTHS. |
| Other Criteria | ANCA-ASSOCIATED VASCULITIS: RENEWAL: CONTINUES TO BENEFIT FROM THERAPY. |
| 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 |

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 INHALED

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 |

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

- BENDAMUSTINE HCL
INTRAVENOUS SOLUTION
- *bendamustine hcl intravenous solution reconstituted*
- 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 OF AT LEAST 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 ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. RENEWAL: 1) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: |

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|----------------------------|--|
| | (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-ADCD

Products Affected

- VEGZELMA

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

BEVACIZUMAB-AWWB

Products Affected

- MVASI

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

BEVACIZUMAB-BVZR

Products Affected

- ZIRABEV

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

BEXAROTENE

Products Affected

- *bexarotene*

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

BINIMETINIB

Products Affected

- MEKTOVI

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

BORTEZOMIB

Products Affected

- *bortezomib injection solution reconstituted*

| 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

- *bosentan*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: INITIAL: 1) DOES NOT HAVE ELEVATED LIVER ENZYMES (ALT, AST) MORE THAN 3 TIMES UPPER LIMIT OF NORMAL (ULN) OR INCREASE IN BILIRUBIN BY 2 OR MORE TIMES ULN, AND 2) NO CONCURRENT USE WITH CYCLOSPORINE A OR GLYBURIDE. RENEWAL: NO CONCURRENT USE WITH CYCLOSPORINE A OR GLYBURIDE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

Formulary ID: 25489
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BOSUTINIB

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND BOSULIF IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| 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 TABLET THERAPY 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-HAEGARDA

Products Affected

- HAEGARDA SUBCUTANEOUS SOLUTION RECONSTITUTED 2000 UNIT, 3000 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/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 CAPSULE

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

| 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 TABLET

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

CAPIVASERTIB

Products Affected

- TRUQAP

| 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 |

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 oral tablet soluble*

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

CERITINIB

Products Affected

- ZYKADIA 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 |

CERTOLIZUMAB PEGOL

Products Affected

- CIMZIA (2 SYRINGE)
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

| 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: 1) PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT, OR 2) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) ONE OF THE FOLLOWING: (A) PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT, OR (B) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |

Formulary ID: 25489
Effective: 01/01/2025
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| PA Criteria | Criteria Details |
|-----------------------|---|
| | <p>MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSO: 1) ONE OF THE FOLLOWING: (A) PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT, OR (B) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS: 1) ONE OF THE FOLLOWING: (A) PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT, OR (B) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. CD: 1) ONE OF THE FOLLOWING: (A) PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT, OR (B) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: STELARA, HUMIRA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA, AS, PSO, NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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| PA Criteria | Criteria Details |
|--------------------------------|------------------|
| 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 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

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

CLOBAZAM-SYMPAZAN

Products Affected

- SYMPAZAN

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

COBIMETINIB

Products Affected

- COTELLIC

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

CORTICOTROPIN

Products Affected

- ACTHAR
- ACTHAR GEL SUBCUTANEOUS AUTO-INJECTOR 40 UNIT/0.5ML, 80 UNIT/ML

| 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 | Yes |

CRIZOTINIB CAPSULE

Products Affected

- XALKORI ORAL CAPSULE

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

CRIZOTINIB PELLETS

Products Affected

- XALKORI ORAL CAPSULE SPRINKLE
150 MG, 20 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | NON-SMALL CELL LUNG CANCER (NSCLC), ANAPLASTIC LARGE CELL LYMPHOMA (ALCL), INFLAMMATORY MYOFIBROBLASTIC TUMOR (IMT); UNABLE TO SWALLOW CAPSULES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DABRAFENIB CAPSULES

Products Affected

- TAFINLAR ORAL CAPSULE

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

DABRAFENIB SUSPENSION

Products Affected

- TAFINLAR ORAL TABLET SOLUBLE

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

DACOMITINIB

Products Affected

- VIZIMPRO

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

DALFAMPRIDINE

Products Affected

- dalfampridine er*

| 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/RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC, METASTATIC HORMONE-SENSITIVE PROSTATE CANCER (MHSPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: NMCRPC, MHSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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Effective: 01/01/2025
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DASATINIB

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*
- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): MUTATIONAL ANALYSIS PRIOR TO INITIATION AND SPRYCEL IS APPROPRIATE PER NCCN GUIDELINE TABLE FOR TREATMENT RECOMMENDATIONS BASED ON BCR-ABL1 MUTATION PROFILE. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | |
| 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 oral tablet*

| 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 |

DENOSUMAB-XGEVA

Products Affected

- XGEVA

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

DEUTETRABENAZINE

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION

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

DICLOFENAC TOPICAL SOLUTION

Products Affected

- *diclofenac sodium external solution 2 %*

| 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 120 mg, 240 mg*
- *dimethyl fumarate starter pack oral capsule delayed release therapy 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 |

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 CAPSULE

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 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: EOSINOPHILIC ASTHMA: BLOOD EOSINOPHIL LEVEL OF 150 TO 1500 CELLS/MCL WITHIN THE PAST 12 MONTHS. EOSINOPHILIC ESOPHAGITIS (EOE): DIAGNOSIS CONFIRMED BY ESOPHAGOGASTRODUODENOSCOPY (EGD) WITH BIOPSY. ATOPIC DERMATITIS (AD): AD COVERING AT LEAST 10 PERCENT OF BODY SURFACE AREA OR AD AFFECTING THE FACE, HEAD, NECK, HANDS, FEET, GROIN, OR INTERTRIGINOUS AREAS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: AD, PRURIGO NODULARIS (PN): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSWNP): PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. EOE: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, ALLERGIST, OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: AD, CRSWNP, EOE, PN: 6 MOS, ASTHMA: 4 MOS. RENEWAL: ALL INDICATIONS: 12 MOS. |
| Other Criteria | INITIAL: AD: 1) INTRACTABLE PRURITUS OR CRACKING/OOZING/BLEEDING OF AFFECTED SKIN, 2) TRIAL OF OR CONTRAINDICATION TO ONE TOPICAL (CORTICOSTEROID, CALCINEURIN INHIBITOR, PDE4 INHIBITOR, OR JAK INHIBITOR), AND 3) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS OR JAK INHIBITORS FOR AD. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY-TOLERATED DOSE OF AN |

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| PA Criteria | Criteria Details |
|-------------|---|
| | <p>INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NO CONCURRENT USE WITH XOLAIR, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. CRSWNP: 1) EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY OR SINUS CT SCAN, 2) INADEQUATELY CONTROLLED DISEASE AS DETERMINED BY USE OF SYSTEMIC STEROIDS IN THE PAST 2 YEARS OR ENDOSCOPIC SINUS SURGERY, 3) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, AND 4) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PN: 1) CHRONIC PRURITIS (ITCH MORE THAN 6 WEEKS), MULTIPLE PRURIGINOUS LESIONS, AND HISTORY OR SIGN OF A PROLONGED SCRATCHING BEHAVIOR, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE TOPICAL (CORTICOSTEROID OR CALCIPOTRIOL). RENEWAL: AD: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS OR JAK INHIBITORS FOR AD. EOE: IMPROVEMENT WHILE ON THERAPY. CRSWNP: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ASTHMA: 1) NO CONCURRENT USE WITH XOLAIR, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS FOR ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE,</p> |

| | |
|----------------------------|--|
| PA Criteria | Criteria Details |
| | OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. PN: IMPROVEMENT OR REDUCTION OF PRURITIS OR PRURIGINOUS LESIONS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DUVELISIB

Products Affected

- COPIKTRA

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

EFLORNITHINE

Products Affected

- IWILFIN

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 24 MONTHS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELACESTRANT

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

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

ELAGOLIX

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 | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS |
| Other Criteria | MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT, AND 2) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND A PROGESTIN-CONTAINING PREPARATION. RENEWAL: 1) IMPROVEMENT IN PAIN ASSOCIATED WITH ENDOMETRIOSIS WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH ANOTHER GNRH-MODULATING AGENT |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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ELRANATAMAB-BCMM

Products Affected

- ELREXFIO SUBCUTANEOUS SOLUTION 44 MG/1.1ML, 76 MG/1.9ML

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | RELAPSED OR REFRACTORY MULTIPLE MYELOMA: RENEWAL: 1) HAS RECEIVED AT LEAST 24 WEEKS OF TREATMENT WITH ELREXFIO, AND 2) HAS RESPONDED TO TREATMENT (PARTIAL RESPONSE OR BETTER), AND HAS MAINTAINED THIS RESPONSE FOR AT LEAST 2 MONTHS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELTROMBOPAG - ALVAIZ

Products Affected

- ALVAIZ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT IS LESS THAN $30 \times 10^9/L$ FROM AT LEAST 2 SEPARATE LABS IN THE LAST 3 MONTHS, OR 2) PLATELET COUNT IS LESS THAN $50 \times 10^9/L$ FROM AT LEAST 2 SEPARATE LABS IN THE LAST 3 MONTHS AND HAD A PRIOR BLEEDING EVENT. |
| 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: ITP: 1) TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS OR IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS) OR SPLEEN TYROSINE KINASE (SYK) INHIBITOR. RENEWAL: ITP: 1) IMPROVEMENT IN PLATELET COUNT FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS OR SYK INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ELTROMBOPAG - PROMACTA

Products Affected

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

| 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 |

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 CAPSULES

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 |

ENTRECTINIB PELLETS

Products Affected

- ROZLYTREK ORAL PACKET

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), SOLID TUMORS: 1) TRIAL OF OR CONTRAINDICATION TO ROZLYTREK CAPSULES MADE INTO AN ORAL SUSPENSION, AND 2) DIFFICULTY OR UNABLE TO SWALLOW CAPSULES. |
| 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 | INITIAL: ALL INDICATIONS: 12 MONTHS. RENEWAL: MCRPC, NMCRPC, MCSPC: 12 MONTHS. |
| Other Criteria | INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NON-METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (NMCSPC): HIGH RISK FOR METASTASIS (I.E. PSA DOUBLING TIME OF 9 MONTHS OR LESS). METASTATIC CRPC (MCRPC), NMCRPC, METASTATIC CSPC (MCSPC), NMCSPC : 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: MCRPC, NMCRPC, MCSPC: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GNRH ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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EPCORITAMAB-BYSP

Products Affected

- EPKINLY

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

EPOETIN ALFA-EPBX

Products Affected

- RETACRIT INJECTION SOLUTION UNIT/ML, 4000 UNIT/ML, 40000
10000 UNIT/ML, 10000 UNIT/ML(1ML), UNIT/ML
2000 UNIT/ML, 20000 UNIT/ML, 3000

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL IS LESS THAN 10G/DL. ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL IS LESS THAN 13G/DL. RENEWAL: 1) CKD IN ADULTS NOT ON DIALYSIS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 2) CKD IN PEDIATRIC PATIENTS: (A) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR (B) HEMOGLOBIN LEVEL HAS APPROACHED OR EXCEEDS 12G/DL AND THE DOSE IS BEING OR HAS BEEN REDUCED/INTERRUPTED TO DECREASE THE NEED FOR BLOOD TRANSFUSIONS. 3) ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. 4) CANCER CHEMOTHERAPY: (A) HEMOGLOBIN LEVEL IS LESS THAN 10 G/DL, OR (B) 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. |

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| PA Criteria | Criteria Details |
|----------------------------|-------------------------------|
| 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 hcl 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 NON-SMALL CELL LUNG CANCER (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 (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

| 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 MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| 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: RHEUMATOID ARTHRITIS (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. |
| 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: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., |

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|----------------------------|--|
| | <p>JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSO: 1) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA, PSA, AS, PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EVEROLIMUS-AFINITOR

Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *torpenz oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

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

EVEROLIMUS-AFINITOR DISPERZ

Products Affected

- *everolimus oral tablet soluble*

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

FECAL MICROBIOTA CAPSULE

Products Affected

- VOWST

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

FEDRATINIB

Products Affected

- INREBIC

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

FENFLURAMINE

Products Affected

- FINTEPLA

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

FENTANYL CITRATE

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

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

FEZOLINETANT

Products Affected

- VEOZAH

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | MENOPAUSAL VASOMOTOR SYMPTOMS (VMS): INITIAL: 1) EXPERIENCES 7 OR MORE HOT FLASHES PER DAY, AND 2) TRIAL OF OR CONTRAINDICATION TO HORMONAL THERAPY (E.G., ESTRADIOL TRANSDERMAL PATCH, ORAL CONJUGATED ESTROGENS). RENEWAL: 1) CONTINUED NEED FOR VMS TREATMENT (I.E., PERSISTENT HOT FLASHES), AND 2) REDUCTION IN VMS FREQUENCY OR SEVERITY DUE TO VEOZAH TREATMENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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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 |

FINERENONE

Products Affected

- KERENDIA

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

FINGOLIMOD

Products Affected

- *fingolimod hcl*

| 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 |

FREMANEZUMAB-VFRM

Products Affected

- AJOVY

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

FRUQUINTINIB

Products Affected

- FRUZAQLA ORAL CAPSULE 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 |

FUTIBATINIB

Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

| 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
- EMGALITY (300 MG DOSE)

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

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GANAXOLONE

Products Affected

- ZTALMY

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

GEFITINIB

Products Affected

- *gefitinib*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC NON-SMALL CELL LUNG CANCER (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

- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous solution prefilled 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 |

GLP1-DULAGLUTIDE

Products Affected

- TRULICITY SUBCUTANEOUS SOLUTION PEN-INJECTOR

| 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 |

GLP1-SEMAGLUTIDE

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE)
- OZEMPIC (1 MG/DOSE)
- OZEMPIC (2 MG/DOSE)
- RYBELSUS

| 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 |

GLP1-TIRZEPATIDE

Products Affected

- MOUNJARO SUBCUTANEOUS SOLUTION PEN-INJECTOR

| 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 |

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 |

GUSELKUMAB

Products Affected

- TREMFYA SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/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, 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. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | INITIAL: PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSO: 1) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: PSO, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, |

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| PA Criteria | Criteria Details |
|----------------------------|--|
| | AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HIGH CONCENTRATION ORAL OPIOID SOLUTIONS

Products Affected

- morphine sulfate (concentrate) oral solution 100 mg/5ml*

| 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 |

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 |

ICATIBANT

Products Affected

- *icatibant acetate subcutaneous solution
prefilled syringe*

| 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 mesylate 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 |

IMETELSTAT

Products Affected

- RYTELO

| 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 |

INFIGRATINIB

Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

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

INFLIXIMAB

Products Affected

- infliximab*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSO: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, STELARA, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE |

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| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>INDICATION. AS: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. MODERATE TO SEVERE CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA, HUMIRA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA, XELJANZ, HUMIRA, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. AS, PSO, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. UC, MODERATE TO SEVERE CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. 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 |

INSULIN SUPPLIES PAYMENT DETERMINATION

Products Affected

- COMFORT ASSIST INSULIN SYRINGE 29G X 1/2" 1 ML
- CVS GAUZE STERILE PAD 2"X2"
- EXEL COMFORT POINT PEN NEEDLE 29G X 12MM
- GLOBAL ALCOHOL PREP EASE
- PREFERRED PLUS INSULIN SYRINGE 28G X 1/2" 0.5 ML
- QC ALCOHOL
- *ra isopropyl alcohol wipes*
- RELI-ON INSULIN SYRINGE 29G 0.3 ML
- ULTICARE INSULIN SYRINGE 30G X 5/16" 0.5 ML

| 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 |

INTERFERON FOR MS-AVONEX

Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED 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 STARTER PACK SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- PLEGRIDY STARTER PACK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- PLEGRIDY SUBCUTANEOUS SOLUTION PEN-INJECTOR
- PLEGRIDY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| 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 | 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 |

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 |

Formulary ID: 25489
Effective: 01/01/2025
H9306_24_DRS_001_002_OE_C

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 |

LANREOTIDE

Products Affected

- LANREOTIDE ACETATE
- SOMATULINE DEPOT
 SUBCUTANEOUS SOLUTION 60
 MG/0.2ML, 90 MG/0.3ML

| 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 ditosylate*

| 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 | VITRAKVI ORAL SOLUTION: 1) TRIAL OF VITRAKVI CAPSULES, OR 2) UNABLE TO TAKE CAPSULE FORMULATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LAZERTINIB

Products Affected

- LAZCLUZE ORAL TABLET 240 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 |

LEDIPASVIR-SOFOSBUVIR

Products Affected

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

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

LENALIDOMIDE

Products Affected

- *lenalidomide*

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

LENVATINIB

Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| 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 |

LETERMIVIR

Products Affected

- PREVYMIS ORAL

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

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LEUPROLIDE

Products Affected

- *leuprolide acetate injection*

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

LEUPROLIDE DEPOT

Products Affected

- LEUPROLIDE ACETATE (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

| 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 (1-MONTH)
- 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 | |

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|--------------------------------|------------------|
| Part B Prerequisite | No |

LEUPROLIDE-LUPRON DEPOT-PED

Products Affected

- LUPRON DEPOT-PED (3-MONTH)
- LUPRON DEPOT-PED (6-MONTH)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR BREAST DEVELOPMENT AND PUBIC HAIR GROWTH. MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) AT TANNER STAGE 2 OR ABOVE FOR GENITAL DEVELOPMENT AND PUBIC HAIR GROWTH. RENEWAL: 1) TANNER STAGING AT INITIAL DIAGNOSIS HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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L-GLUTAMINE

Products Affected

- *l-glutamine oral packet*

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

LIDOCAINE OINTMENT

Products Affected

- *lidocaine external ointment 5 %*

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

LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*
- *lidocan*
- ZTLIDO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | 1) PAIN ASSOCIATED WITH POST-HERPETIC NEURALGIA, 2) NEUROPATHY DUE TO DIABETES MELLITUS, 3) CHRONIC BACK PAIN, OR 4) OSTEOARTHRITIS OF THE KNEE OR HIP. |
| 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 external 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 |

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 |

LOTILANER

Products Affected

- XDEM VY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | DEMODEX BLEPHARITIS: 18 YEARS OF AGE OR OLDER |
| Prescriber Restrictions | |
| Coverage Duration | 6 WEEKS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUMACFTOR-IVACFTOR

Products Affected

- 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: 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 |

MACITENTAN

Products Affected

- OPSUMIT

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

MARIBAVIR

Products Affected

- LIVTENCITY

| 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 |

MECASERMIN

Products Affected

- INCRELEX

| 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 |

MECHLORETHAMINE

Products Affected

- VALCHLOR

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

MEPOLIZUMAB

Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40 MG/0.4ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL OF AT LEAST 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. CRSWNP: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: ASTHMA: 4 MO. CRSWNP: 6 MO. OTHERS: 12 MO. RENEWAL: CRSWNP, ASTHMA: 12 MO. |
| Other Criteria | INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, 2) ONE OF THE FOLLOWING: (A) AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR |

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|----------------------------|---|
| | <p>OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. CRSWNP: 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: ASTHMA: 1) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR (D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. CRSWNP: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</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

- *mifepristone oral tablet 300 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CUSHINGS SYNDROME (CS): INITIAL: DIAGNOSIS CONFIRMED BY: 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: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/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 THERAPY, 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 |

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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 |

MOMELOTINIB

Products Affected

- OJAARA

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

MOSUNETUZUMAB-AXGB

Products Affected

- LUNSUMIO

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

NARCOLEPSY AGENTS

Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

| 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 |

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

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

NINTEDANIB

Products Affected

- OFEV

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) BASELINE FORCED VITAL CAPACITY (FVC) AT LEAST 50% OF PREDICTED VALUE. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 40% OF PREDICTED VALUE. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (PF-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 45% OF PREDICTED VALUE. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL (ALL INDICATIONS): 12 MOS. |
| Other Criteria | INITIAL: IPF: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ESBRIET (PIRFENIDONE). SSC-ILD: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., HEART FAILURE/FLUID OVERLOAD, DRUG-INDUCED LUNG TOXICITY, RECURRENT ASPIRATION), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ACTEMRA |

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|----------------------------|--|
| | SUBQ. PF-ILD: LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENERD/PROGRESSEDE DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILD (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE). RENEWAL: IPF, SSC-ILD, PF-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIRAPARIB

Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

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

NIRAPARIB-ABIRATERONE

Products Affected

- AKEEGA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIROGACESTAT

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 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 |

NITISINONE

Products Affected

- *nitisinone*

| 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 |

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 |

NOGAPENDEKIN ALFA

Products Affected

- ANKTIVA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 40 MONTHS |
| Other Criteria | |
| 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

| 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) AT HIGH RISK FOR WEIGHT GAIN, AND 2) TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF LURASIDONE OR ONE OF THE FOLLOWING ORAL ANTIPSYCHOTICS: RISPERIDONE, CLOZAPINE TABLET, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE. BIPOLAR I: 1) AT HIGH RISK FOR 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 |

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OLAPARIB

Products Affected

- LYNPARZA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER: MEDICATION WILL BE USED AS MONOTHERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. 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 |

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OLUTASIDENIB

Products Affected

- REZLIDHIA

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

OMACETAXINE

Products Affected

- SYNRIBO

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

OMALIZUMAB

Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: ASTHMA: POSITIVE SKIN PRICK OR BLOOD TEST (E.G., ELISA, FEIA) TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL OF AT LEAST 30 IU/ML. FOOD ALLERGY: 1) IGE SERUM LEVEL OF AT LEAST 30 IU/ML, AND 2) ALLERGEN SPECIFIC IGE SERUM LEVEL OF AT LEAST 6 KUA/L TO AT LEAST ONE FOOD, OR POSITIVE SKIN PRICK TEST TO AT LEAST ONE FOOD, OR POSITIVE MEDICALLY MONITORED FOOD CHALLENGE TO AT LEAST ONE FOOD. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL/RENEWAL: CHRONIC SPONTANEOUS URTICARIA (CSU): PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST. INITIAL: CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSWNP): 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. FOOD ALLERGY: PRESCRIBED BY OR IN CONSULTATION WITH ALLERGIST OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: ASTHMA: 4 MO. CSU, CRSWNP: 6 MO. FOOD ALLERGY: 12 MO. RENEWAL: SEE OTHER CRITERIA |
| Other Criteria | INITIAL: CSU: 1) TRIAL OF AND MAINTAINED ON, OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE AND 2) STILL EXPERIENCES HIVES OR ANGIOEDEMA ON MOST DAYS OF THE WEEK FOR AT LEAST 6 WEEKS. CRSWNP: 1) A 56 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, 2) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED AGENT: NUCALA, DUPIXENT, AND 3) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 |

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| PA Criteria | Criteria Details |
|-------------|---|
| | <p>INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, 2) ONE OF THE FOLLOWING: (A) AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NO CONCURRENT USE WITH DUPIXENT, TEZSPIRE, OR ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. FOOD ALLERGY: 1) CONCURRENT USE WITH AN ACTIVE PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTOR/INJECTION, AND 2) NO CONCURRENT USE WITH PEANUT-SPECIFIC IMMUNOTHERAPY. RENEWAL: CSU: 12 MONTHS APPROVAL: MAINTAINED ON OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE. CRSWNP: 12 MONTHS APPROVAL: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ASTHMA: 12 MONTHS APPROVAL: 1) NO CONCURRENT USE WITH DUPIXENT, TEZSPIRE, OR ANTI-IL5 BIOLOGICS WHEN USED FOR 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. FOOD ALLERGY: 24 MONTHS APPROVAL: 1) PERSISTENT IGE-MEDIATED FOOD ALLERGY, 2) CONCURRENT USE WITH AN ACTIVE PRESCRIPTION FOR EPINEPHRINE AUTO-</p> |

| | |
|----------------------------|--|
| PA Criteria | Criteria Details |
| | INJECTOR/INJECTION, AND 3) NO CONCURRENT USE WITH PEANUT-SPECIFIC IMMUNOTHERAPY. |
| 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 | NON-SMALL CELL LUNG CANCER (NSCLC) WITH EGFR EXON 19 DELETIONS OR EXON 21 L858R MUTATIONS, OR EGFR T790M MUTATION: NO CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OXANDROLONE

Products Affected

- *oxandrolone oral*

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

PACRITINIB

Products Affected

- VONJO

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

PALBOCICLIB

Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE PREFERRED AGENTS, WHERE INDICATIONS ALIGN: KISQALI, VERZENIO. |
| 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

- *pazopanib hcl*

| 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 |

PEGFILGRASTIM - APGF

Products Affected

- NYVEPRIA

| 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 |

PEGFILGRASTIM-NEULASTA ONPRO

Products Affected

- NEULASTA ONPRO

| 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 |

PEGINTERFERON ALFA-2A

Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED 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 |

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 INTRAVENOUS SOLUTION

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

PEMIGATINIB

Products Affected

- PEMAZYRE

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

PENICILLAMINE TABLET

Products Affected

- *penicillamine oral tablet*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: CYSTINURIA: HAS NEPHROLITHIASIS AND ONE OF THE FOLLOWING: 1) STONE ANALYSIS SHOWING PRESENCE OF CYSTINE, 2) PRESENCE OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, OR 3) FAMILY HISTORY OF CYSTINURIA AND POSITIVE CYANIDE-NITROPRUSSIDE SCREENING. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: WILSONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST. CYSTINURIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST. RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| Coverage Duration | INITIAL: 12 MONTHS, RENEWAL: LIFETIME. |
| Other Criteria | INITIAL: WILSONS DISEASE: 1) LEIPZIG SCORE OF 4 OR GREATER. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, AND 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS DISEASE, CYSTINURIA: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |

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|---------------------|------------------|
| 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 ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

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

PIRFENIDONE

Products Affected

- *pirfenidone oral 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 |

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PIRTOBRUTINIB

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

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

POMALIDOMIDE

Products Affected

- POMALYST

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

PONATINIB

Products Affected

- ICLUSIG

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

POSACONAZOLE TABLET

Products Affected

- *posaconazole oral tablet delayed release*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE, PROPHYLAXIS: 6 MONTHS. TREATMENT: 12 WEEKS. |
| Other 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 |

PYRIMETHAMINE

Products Affected

- *pyrimethamine oral*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | TOXOPLASMOSIS: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST. |
| Coverage Duration | TOXOPLASMOSIS: INITIAL: 8 WEEKS, RENEWAL: 6 MOS. |
| Other Criteria | TOXOPLASMOSIS: RENEWAL: ONE OF THE FOLLOWING: (1) PERSISTENT CLINICAL DISEASE (HEADACHE, NEUROLOGICAL SYMPTOMS, OR FEVER) AND PERSISTENT RADIOGRAPHIC DISEASE (ONE OR MORE MASS LESIONS ON BRAIN IMAGING), OR (2) CD4 COUNT LESS THAN 200 CELLS/MM3 AND CURRENTLY TAKING AN ANTI-RETROVIRAL THERAPY IF HIV POSITIVE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

QUININE

Products Affected

- *quinine sulfate oral*

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

QUIZARTINIB

Products Affected

- VANFLYTA

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

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 |

REPOTRECTINIB

Products Affected

- AUGTYRO

| 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 OF AT LEAST 150 CELLS/MCL WITHIN THE PAST 12 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| Coverage Duration | ASTHMA: INITIAL: 4 MONTHS. RENEWAL: 12 MONTHS |
| Other Criteria | ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: (A) DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, (B) ANY NIGHT WAKING DUE TO ASTHMA, (C) SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, (D) ANY ACTIVITY LIMITATION DUE TO ASTHMA, 3) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT, AND 4) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR ASTHMA. RENEWAL: 1) NO CONCURRENT USE WITH XOLAIR, DUPIXENT, TEZSPIRE, OR OTHER ANTI-IL5 BIOLOGICS WHEN USED FOR |

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| | ASTHMA, 2) CONTINUED USE OF ICS AND ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RETIFANLIMAB-DLWR

Products Affected

- ZYNYZ

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

RIBOCICLIB

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)

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

RIBOCICLIB-LETROZOLE

Products Affected

- KISQALI FEMARA (200 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)

| 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 |

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, HEPATIC ENCEPHALOPATHY (HE): 12 MOS. IBS-D: 8 WKS. |
| Other Criteria | HE: TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RILONACEPT

Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | <p>CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES.</p> <p>DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE IL1RN GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR), AND 2) ONE OF THE FOLLOWING: PUSTULAR PSORIASIS-LIKE RASHES, OSTEOMYELITIS, ABSENCE OF BACTERIAL OSTEOMYELITIS, ONYCHOMADESIS. RECURRENT PERICARDITIS (RP): TWO OF THE FOLLOWING: CHEST PAIN CONSISTENT WITH PERICARDITIS, PERICARDIAL FRICTION RUB, ECG SHOWING DIFFUSE ST-SEGMENT ELEVATION OR PR-SEGMENT DEPRESSION, NEW OR WORSENING PERICARDIAL EFFUSION.</p> |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CAPS, DIRA: LIFETIME. RP: 12 MONTHS. |
| Other Criteria | <p>CAPS: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS.</p> <p>DIRA: 1) NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS, AND 2) TRIAL OF THE PREFERRED AGENT: KINERET. RP: 1) HAD AN EPISODE OF ACUTE PERICARDITIS, 2) SYMPTOM-FREE</p> |

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|----------------------------|--|
| PA Criteria | Criteria Details |
| | FOR 4 TO 6 WEEKS, AND 3) NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RIMEGEPANT

Products Affected

- NURTEC

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

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| PA Criteria | Criteria Details |
|----------------------------|-------------------------------|
| 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): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) (WHO GROUP 4): WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: PAH, CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PAH: NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE (PDE) INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. CTEPH: 1) NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PDE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS, AND 2) NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL: PAH, CTEPH: NO CONCURRENT USE WITH NITRATES, NITRIC OXIDE DONORS, PDE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

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| PA Criteria | Criteria Details |
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| 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
- SKYRIZI (150 MG DOSE)
- SKYRIZI PEN

| 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) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. CD: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY (E.G., |

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| PA Criteria | Criteria Details |
|----------------------------|--|
| | CORTICOSTEROID [E.G., BUDESONIDE, METHYLPREDNISOLONE], AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, MESALAMINE), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: PSO, PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB AND HYALURONIDASE HUMAN-SQ

Products Affected

- RITUXAN HYCELA

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

RITUXIMAB-ABBS

Products Affected

- TRUXIMA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA: 12 MO. CLL: 6 MO. |
| Other Criteria | RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB-ARRX

Products Affected

- RIABNI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA: 12 MO. CLL: 6 MO. |
| Other Criteria | RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RITUXIMAB-PVVR

Products Affected

- RUXIENCE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | RA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NON-HODGKINS LYMPHOMA (NHL), CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST. |
| Coverage Duration | RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA: 12 MO. CLL: 6 MO. |
| Other Criteria | RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. 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 |

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: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SAPROPTERIN

Products Affected

- *javygtor oral tablet*
- *sapropterin dihydrochloride oral tablet*

| 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 |

SECUKINUMAB IV

Products Affected

- COSENTYX INTRAVENOUS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: 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: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR A 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: PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS, NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: PSA, AS, NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |

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

SECUKINUMAB SQ

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX UNOREADY

| 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, HIDRADENITIS SUPPURATIVA (HS): 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: HS: 4 MONTHS, ALL OTHER INDICATIONS: 6 MONTHS. RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: PSO: 1) ONE OF THE FOLLOWING: (A) AT LEAST A 3 MONTH TRIAL OF ONE ORAL IMMUNOSUPPRESSANT (CYCLOSPORINE, METHOTREXATE, TACROLIMUS) OR PUVA (PHOTOTHERAPY) FOR THE TREATMENT OF PSO, (B) CONTRAINDICATION OR INTOLERANCE TO BOTH IMMUNOSUPPRESSANT AND PUVA FOR THE TREATMENT OF PSO, OR (C) PATIENT IS SWITCHING FROM A DIFFERENT BIOLOGIC, PDE-4 INHIBITOR, OR JAK INHIBITOR FOR THE SAME INDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |

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|----------------------------|---|
| | <p>MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS, NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ERA: TRIAL OF OR CONTRAINDICATION TO ONE NSAID, SULFASALAZINE, OR METHOTREXATE. HS: NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR HS OR OTHER IL-17 INHIBITORS FOR ANY INDICATION. RENEWAL: PSO, PSA, AS, NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ERA: CONTINUES TO BENEFIT FROM THE MEDICATION. HS: 1) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR HS OR OTHER IL-17 INHIBITORS FOR ANY INDICATION, AND 2) CONTINUES TO BENEFIT FROM THE MEDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SELEXIPAG

Products Affected

- UPTRAVI INTRAVENOUS
- UPTRAVI ORAL TABLET 1000 MCG, 1200 MCG, 1400 MCG, 1600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI TITRATION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS |
| Other Criteria | PAH: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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SELINEXOR

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

| 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
- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

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

SELUMETINIB

Products Affected

- KOSELUGO ORAL CAPSULE 10 MG,
25 MG

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

SILDENAFIL TABLET

Products Affected

- sildenafil citrate oral tablet 20 mg*

| 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 |

SIPONIMOD

Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK

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

SIROLIMUS PROTEIN-BOUND

Products Affected

- FYARRO

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

SODIUM OXYBATE-XYREM

Products Affected

- sodium oxybate*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: CATAPLEXY IN NARCOLEPSY, 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: 1) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT, 2) AGES 18 YEARS OR OLDER: TRIAL, FAILURE OF, OR CONTRAINDICATION TO A FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, OR SUNOSI AND ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, AND 3) AGES 7 TO 17 YEARS: TRIAL, FAILURE OF, OR CONTRAINDICATION TO ONE GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. CATAPLEXY IN NARCOLEPSY: NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. RENEWAL: CATAPLEXY IN NARCOLEPSY, EDS IN NARCOLEPSY: 1) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH A SEDATIVE HYPNOTIC AGENT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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SOFOSBUVIR/VELPATASVIR

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| Other Criteria | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, HIV REGIMEN THAT CONTAINS EFAVIRENZ, ROSUVASTATIN AT DOSES ABOVE 10MG, 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 | |
| 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 | |
| Part B Prerequisite | No |

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SOMATROPIN - NORDITROPIN

Products Affected

- NORDITROPIN FLEXPRO
SUBCUTANEOUS SOLUTION PEN-
INJECTOR

| 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 BELOW THE MEAN HEIGHT FOR CHILDREN OF THE SAME AGE AND GENDER. PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS. |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL/RENEWAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | INITIAL: ADULT GHD: GHD ALONE OR ASSOCIATED WITH MULTIPLE HORMONE DEFICIENCIES (HYPOPITUITARISM), AS A RESULT OF PITUITARY DISEASE, HYPOTHALAMIC DISEASE, SURGERY, RADIATION THERAPY, OR TRAUMA, OR FOR CONTINUATION OF THERAPY FROM CHILDHOOD ONSET GHD. 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 HAS NOT COMPLETED PREPUBERTAL GROWTH. ISS, SGA, TS, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF |

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| | |
|----------------------------|---|
| PA Criteria | Criteria Details |
| | THE WRIST AND HAND. PWS: IMPROVEMENT IN BODY COMPOSITION. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SOMATROPIN - SEROSTIM

Products Affected

- SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 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: ONE OF THE FOLLOWING 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) 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 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) INADEQUATE RESPONSE TO ONE PREVIOUS THERAPY (E.G., MEGACE, APPETITE STIMULANTS, ANABOLIC STEROIDS). RENEWAL: 1) CLINICAL BENEFIT IN MUSCLE MASS AND WEIGHT. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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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 tosylate*

| 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 |

SOTATERCEPT-CSRK

Products Affected

- WINREVAIR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| Age Restrictions | |
| Prescriber Restrictions | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| Coverage Duration | INITIAL/RENEWAL: 12 MONTHS. |
| Other Criteria | PAH: INITIAL: 1) ON BACKGROUND PAH THERAPY (FOR AT LEAST 3 MONTHS) WITH AT LEAST TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: A) ORAL ENDOTHELIN RECEPTOR ANTAGONIST, B) ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, C) ORAL CGMP STIMULATOR, D) IV/SQ PROSTACYCLIN, OR 2) ON ONE AGENT FROM ONE OF THE ABOVE DRUG CLASSES, AND HAS A CONTRAINDICATION OR INTOLERANCE TO ALL OF THE OTHER DRUG CLASSES. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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SOTORASIB

Products Affected

- LUMAKRAS ORAL TABLET 120 MG,
320 MG

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

STIRIPENTOL

Products Affected

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

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

SUNITINIB

Products Affected

- *sunitinib malate*

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

TADALAFIL - ADCIRCA, ALYQ

Products Affected

- *alyq*

| 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 |

TADALAFIL-CIALIS

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

| 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 |

TALAZOPARIB

Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | ADVANCED OR METASTATIC BREAST CANCER: 1) HAS BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING, AND 2) IF HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER, RECEIVED PRIOR TREATMENT WITH ENDOCRINE THERAPY OR IS CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TALQUETAMAB-TGVS

Products Affected

- TALVEY

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

TARLATAMAB-DLLE

Products Affected

- IMDELLTRA

| 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 |

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 |

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 |

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 |

TERIPARATIDE

Products Affected

- TERIPARATIDE SUBCUTANEOUS SOLUTION PEN-INJECTOR 620 MCG/2.48ML

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 24 MONTHS |
| Other Criteria | OSTEOPOROSIS: HAS NOT RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY, UNLESS REMAINS AT OR HAS RETURNED TO HAVING A HIGH RISK FOR FRACTURE. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TESTOSTERONE

Products Affected

- *testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)*

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

TESTOSTERONE CYPIONATE

Products Affected

- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*

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

TESTOSTERONE ENANTHATE

Products Affected

- *testosterone enanthate intramuscular solution*
- XYOSTED

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | MALE HYPOGONADISM: INITIAL: CONFIRMED BY: 1) AT LEAST TWO TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 NG/DL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL: MALE DELAYED PUBERTY: 6MO, MALE HYPOGONADISM: 12 MO. OTHER INDICATIONS: 12 MO. |
| Other Criteria | INITIAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PROSTATE SPECIFIC ANTIGEN (PSA) HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING. RENEWAL: MALE HYPOGONADISM: 1) 40 YEARS OR OLDER: PSA HAS BEEN EVALUATED FOR PROSTATE CANCER SCREENING, AND 2) IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. MALE DELAYED PUBERTY: HAS NOT RECEIVED MORE THAN TWO 6-MONTH COURSES OF TESTOSTERONE REPLACEMENT THERAPY |
| 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 |

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 |

TISLELIZUMAB-JSGR

Products Affected

- TEVIMBRA

| 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 | CORONAVIRUS DISEASE 2019 (COVID-19) IN HOSPITALIZED ADULTS |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. |
| Coverage Duration | INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS. |
| Other Criteria | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ, RINVOQ, ORENCIA. PJIA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, XELJANZ IR, ORENCIA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. SJIA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA, SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |

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| | |
|----------------------------|--|
| PA Criteria | Criteria Details |
| | MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. |
| 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 | 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 |

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 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PSA, PCJIA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. UC: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY (E.G., CORTICOSTEROID [E.G., BUDESONIDE, |

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| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>METHYLPREDNISOLONE], AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, MESALAMINE), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA, AS, PCJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TOPICAL TRETINOIN

Products Affected

- *tretinoin external cream*

| 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 |

TORIPALIMAB-TPZI

Products Affected

- LOQTORZI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | NASOPHARYNGEAL CARCINOMA (NPC): FIRST LINE TREATMENT: 24 MOS, PREVIOUSLY TREATED: LIFETIME. |
| 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 |

TOVORAFENIB

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA 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 |

TRAMETINIB SOLUTION

Products Affected

- MEKINIST ORAL SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 MONTHS |
| Other Criteria | UNRESECTABLE OR METASTATIC MELANOMA, MELANOMA, METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC), LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER (ATC), UNRESECTABLE OR METASTATIC SOLID TUMOR, LOW-GRADE GLIOMA (LGG): UNABLE TO SWALLOW MEKINIST TABLETS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRAMETINIB TABLET

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-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-HYALURONIDASE-OYSK

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-PKRB

Products Affected

- HERZUMA

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

TRASTUZUMAB-QYYP

Products Affected

- TRAZIMERA

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

TREMELIMUMAB-ACTL

Products Affected

- IMJUDO

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

TRIENTINE CAPSULE

Products Affected

- *trientine hcl oral capsule 250 mg*

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

TRIFLURIDINE/TIPIRACIL

Products Affected

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

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

TRIPTORELIN-TRELSTAR

Products Affected

- TRELSTAR MIXJECT

| 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: 1) TRIAL OF OR CONTRAINDICATION TO ONE TRIPTAN (E.G., SUMATRIPTAN, RIZATRIPTAN), AND 2) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT. RENEWAL: 1) NO CONCURRENT USE WITH OTHER CGRP INHIBITORS FOR ACUTE MIGRAINE TREATMENT, AND 2) ONE OF THE FOLLOWING: (A) IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE, OR (B) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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UPADACITINIB

Products Affected

- RINVOQ
- RINVOQ LQ

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | INITIAL: NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI). ATOPIC DERMATITIS (AD): ATOPIC DERMATITIS COVERING AT LEAST 10 PERCENT OF BODY SURFACE AREA OR ATOPIC DERMATITIS AFFECTING THE FACE, HEAD, NECK, HANDS, FEET, GROIN, OR INTERTRIGINOUS AREAS |
| Age Restrictions | |
| Prescriber Restrictions | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. AD: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST. ULCERATIVE COLITIS (UC), CROHNS DISEASE (CD): 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 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PSA: 1) TRIAL OF OR CONTRAINDICATION TO ONE DMARD, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AD: 1) INTRACTABLE PRURITUS |

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| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>OR CRACKING/OOZING/BLEEDING OF AFFECTED SKIN, 2) TRIAL OF OR CONTRAINDICATION TO A TOPICAL CORTICOSTEROID, TOPICAL CALCINEURIN INHIBITOR, TOPICAL PDE4 INHIBITOR, OR TOPICAL JAK INHIBITOR, AND 3) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR ATOPIC DERMATITIS OR OTHER JAK INHIBITORS FOR ANY INDICATION. UC, CD: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY (E.G., CORTICOSTEROID [E.G., BUDESONIDE, METHYLPREDNISOLONE], AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, MESALAMINE), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. AS, NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. AD: 1) IMPROVEMENT WHILE ON THERAPY, AND 2) NO CONCURRENT USE WITH OTHER SYSTEMIC BIOLOGICS FOR ATOPIC DERMATITIS OR OTHER JAK INHIBITOR FOR ANY INDICATION. PSA, AS, NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. UC, CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION.</p> |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

USTEKINUMAB

Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED 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 |

USTEKINUMAB IV

Products Affected

- STELARA INTRAVENOUS

| 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: 1) TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY (E.G., CORTICOSTEROID [E.G., BUDESONIDE, METHYLPREDNISOLONE], AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, MESALAMINE), AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE- 4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VALBENAZINE

Products Affected

- INGREZZA ORAL CAPSULE
- INGREZZA ORAL CAPSULE SPRINKLE
- INGREZZA ORAL CAPSULE THERAPY PACK

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

VANDETANIB

Products Affected

- CAPRELSA ORAL TABLET 100 MG,
300 MG

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

VEMURAFENIB

Products Affected

- ZELBORAF

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

VENETOCLAX

Products Affected

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

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

VERICIGUAT

Products Affected

- VERQUVO

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | INITIAL/RENEWAL:12 MONTHS. |
| Other Criteria | HEART FAILURE (HF): INITIAL: 1) NO CONCURRENT USE WITH LONG-ACTING NITRATES OR NITRIC OXIDE DONORS, RIOCIQUAT, OR PDE-5 INHIBITORS, 2) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED SGLT-2 INHIBITOR, AND 3) TRIAL OF OR CONTRAINDICATION TO ONE AGENT FROM ANY OF THE FOLLOWING STANDARD OF CARE CLASSES: (A) ACE INHIBITOR, ARB, OR ARNI, (B) BETA BLOCKER (I.E., BISOPROLOL, CARVEDILOL, METOPROLOL SUCCINATE), OR (C) ALDOSTERONE ANTAGONIST (I.E., SPIRONOLACTONE, EPLERENONE). RENEWAL: NO CONCURRENT USE WITH LONG-ACTING NITRATES OR NITRIC OXIDE DONORS, RIOCIQUAT, OR PDE-5 INHIBITORS. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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VIGABATRIN

Products Affected

- *vigabatin*
- *vigadrone*
- *vigpoder*

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

VISMODEGIB

Products Affected

- ERIVEDGE

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

VORASIDENIB

Products Affected

- VORANIGO

| 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 reconstituted*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | CANDIDA INFECTIONS: 3 MOS. CONTINUATION OF THERAPY, ALL OTHER INDICATIONS: 6 MOS. |
| Other Criteria | CANDIDA INFECTIONS: 1) TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE, AND 2) UNABLE TO SWALLOW TABLETS. ALL INDICATIONS EXCEPT ESOPHAGEAL CANDIDIASIS: UNABLE 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 |

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 |

ZURANOLONE

Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 14 DAYS |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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