# 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 (WITH MALTOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. |
| **Coverage Duration** | RA, PJIA, PSA: INITIAL: 6 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: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. |

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

# ABATACEPT SQ

## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | INITIAL: RA: 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: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. |

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

# ABEMACICLIB

## Products Affected

- VERZENIO

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

# ABIRATERONE

## Products Affected

- *abiraterone*
- *abirtega*

| 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
- CALQUENCE (ACALABRUTINIB MAL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | PREVIOUSLY TREATED MANTLE CELL LYMPHOMA: INTOLERANCE TO BRUKINSA. CHRONIC LYMPHOCYTIC LEUKEMIA OR SMALL LYMPHOCYTIC LYMPHOMA: INTOLERANCE TO BRUKINSA OR IMBRUVICA. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ADAGRASIB

## Products Affected

- KRAZATI

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

# ADALIMUMAB

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, 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: 12 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RHEUMATOID ARTHRITIS (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. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. HS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR HS. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, HS, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |

| PA Criteria | Criteria Details |
|---|---|
| | MOLECULES FOR PJIA. PSA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ADALIMUMAB-AATY

### Products Affected

- YUFLYMA(CF)
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR

| 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, SCALP, 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: 12 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RHEUMATOID ARTHRITIS (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. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. HS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR HS. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, HS, UVEITIS: CONTINUES TO BENEFIT FROM MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR |

| PA Criteria | Criteria Details |
|---|---|
| | PJIA. PSA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. PSO: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ADALIMUMAB-ADBM

### Products Affected

- CYLTEZO(CF)
- CYLTEZO(CF) PEN
- CYLTEZO(CF) PEN CROHN'S-UC-HS
- CYLTEZO(CF) PEN PSORIASIS-UV

| 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, SCALP, 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: 12 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RHEUMATOID ARTHRITIS (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. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. HS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR HS. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, HS, UVEITIS: CONTINUES TO BENEFIT FROM MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR |

| PA Criteria | Criteria Details |
|---|---|
| | PJIA. PSA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. PSO: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **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 ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

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

# AMBRISENTAN

## Products Affected

- *ambrisentan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS. |
| **Other Criteria** | PAH: INITIAL: DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS. |
| **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

| 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/CYLTEZO/YUFLYMA, 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. |

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

# APALUTAMIDE

## Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

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

# APOMORPHINE

## Products Affected

- *apomorphine*

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

# APOMORPHINE - ONAPGO

## Products Affected

- ONAPGO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| **Coverage Duration** | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | PD: INITIAL: 1) RESPONSIVE TO LEVODOPA, 2) CURRENT MEDICATION REGIMEN, INCLUDING LEVODOPA, HAS BEEN AT A STABLE DOSE FOR AT LEAST 28 DAYS, 3) MOTOR SYMPTOMS ARE CURRENTLY UNCONTROLLED (DEFINED AS AN AVERAGE OFF TIME OF AT LEAST 3 HOURS/DAY, FOR AT LEAST 2 HOURS EACH DAY), AND 4) DOES NOT HAVE ANY OF THE FOLLOWING: ORTHOSTATIC HYPOTENSION, HISTORY OF PROLONGED QTC (GREATER THAN 450 MSEC FOR MALE OR GREATER THAN 470 MSEC FOR FEMALE), ACTIVE OR UNCONTROLLED PSYCHOSIS, ACTIVE OR UNCONTROLLED DEPRESSION. RENEWAL: IMPROVEMENT IN MOTOR SYMPTOMS WHILE ON THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# APOMORPHINE - SL

## Products Affected

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

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

# APREMILAST

## Products Affected

- OTEZLA
- OTEZLA STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: MILD PLAQUE PSORIASIS (PSO): 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, SCALP, OR GENITAL AREA. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. BEHCETS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 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 FOR MODERATE TO SEVERE PSO. 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: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR 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 FOR MODERATE TO SEVERE PSO. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ARIMOCLOMOL

## Products Affected

- MIPLYFFA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | NIEMANN-PICK DISEASE TYPE C (NPC): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEUROLOGIST OR GENETICIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | NPC: RENEWAL: IMPROVEMENT OR SLOWING OF DISEASE PROGRESSION. |
| **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 |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PREVIOUSLY TREATED OR T315I MUTATION 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PERINATAL/INFANTILE-ONSET HPP: 1) 6 MONTHS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALKALINE PHOSPHATASE (ALP) LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PYRIDOXAL-5'-PHOSPHATE (PLP) LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC CHEST DEFORMITY, (II) CRANIOSYNOSTOSIS, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) HISTORY OF VITAMIN B6 DEPENDENT SEIZURES, (V) NEPHROCALCINOSIS OR HISTORY OF ELEVATED SERUM CALCIUM, (VI) HISTORY OR PRESENCE OF NON-TRAUMATIC POSTNATAL FRACTURE AND DELAYED FRACTURE HEALING. JUVENILE-ONSET HPP: 1) 18 YEARS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TNSALP ALPL GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALP LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PLP LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PEA LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC DEFORMITIES, (II) PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 YEARS OF AGE, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) HISTORY OR PRESENCE OF NON-TRAUMATIC FRACTURES OR DELAYED FRACTURE HEALING. ALL INDICATIONS: 1) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE, 2) CALCIUM OR PHOSPHATE LEVELS ARE NOT BELOW THE NORMAL RANGE, 3) |
| | NOT HAVE A TREATABLE FORM OF RICKETS. RENEWAL: ALL INDICATIONS: 1) IMPROVEMENT IN THE SKELETAL CHARACTERISTICS OF HPP, AND 2) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# ATEZOLIZUMAB

## Products Affected

- TECENTRIQ

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

# ATEZOLIZUMAB-HYALURONIDASE-TQJS

## Products Affected

- TECENTRIQ HYBREZA

| 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 |

# 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 |

# AVATROMBOPAG

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | CHRONIC IMMUNE THROMBOCYTOPENIA (CITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS AND A PRIOR BLEEDING EVENT. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: CHRONIC LIVER DISEASE (CLD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, ENDOCRINOLOGIST, OR SURGEON. CITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| **Coverage Duration** | CLD: 1 MONTH. CITP: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| **Other Criteria** | INITIAL: CLD: 1) PLANNED PROCEDURE 10 TO 13 DAYS AFTER INITIATION OF DOPTELET, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). CITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR HAD INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS OR SPLEEN TYROSINE KINASE (SYK) INHIBITOR. RENEWAL: CITP: 1) IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH OTHER TPO-RAS OR SYK INHIBITOR. |
| **Indications** | All FDA-approved Indications. |

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

# AXATILIMAB-CSFR

## Products Affected

- NIKTIMVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required 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 |

# BECAPLERMIN

## Products Affected

- REGRANEX

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

# BEDAQUILINE

## Products Affected

- SIRTURO

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

# BELIMUMAB

## 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 intravenous recon soln*
- BENDAMUSTINE INTRAVENOUS SOLUTION
- BENDEKA

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

# BENRALIZUMAB

## 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/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 2) ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS, OR 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. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA): NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-2 INHIBITOR) FOR EGPA. 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 ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. EGPA: 1) REDUCTION IN EGPA SYMPTOMS COMPARED TO BASELINE OR ABILITY TO REDUCE/ELIMINATE CORTICOSTEROID USE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR EGPA. |
| **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*
- BORUZU

| 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 |

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

# BRIGATINIB

## Products Affected

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

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

# C1 ESTERASE INHIBITOR-CINRYZE

## Products Affected

- CINRYZE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTING: C1INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, ALLERGIST, OR PULMONOLOGIST. |
| **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. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# C1 ESTERASE INHIBITOR-HAEGARDA

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTING: C1INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, ALLERGIST OR PULMONOLOGIST. |
| **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 ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

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

# CABOZANTINIB 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 |

# CANAKINUMAB

## Products Affected

- ILARIS (PF)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): 1) ONE OF THE FOLLOWING: (A) GENETIC TEST FOR GAIN-OF-FUNCTION MUTATIONS IN THE NLRP3 GENE, OR (B) HAS INFLAMMATORY MARKERS (I.E., ELEVATED CRP, ESR, SERUM AMYLOID A PROTEIN (SAA) OR S100 PROTEINS), AND 2) TWO OF THE FOLLOWING: URTICARIAL-LIKE RASH (NEUTROPHILIC DERMATITIS), COLD-TRIGGERED EPISODES, SENSORINEURAL HEARING LOSS, MUSCULOSKELETAL SYMPTOMS, CHRONIC ASEPTIC MENINGITIS, SKELETAL ABNORMALITIES. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA), ADULT-ONSET STILLS DISEASE (AOSD): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST. GOUT: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. RENEWAL: GOUT: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. |
| **Coverage Duration** | INITIAL: AOSD/SJIA: 6 MO, CAPS: LIFETIME, ALL OTHER DIAGNOSES: 12 MO. RENEWAL: AOSD/SJIA/GOUT: 12 MO |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: CAPS: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. AOSD: 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 AOSD. SJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. GOUT: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. RENEWAL: AOSD: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AOSD. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. GOUT: 1) NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS, AND 2) IMPROVEMENT IN GOUT FLARES. |
| **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 |

# CAPLACIZUMAB YHDP

## Products Affected

- CABLIVI INJECTION KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | ACQUIRED THROMBOTIC THROMBOCYTOPENIA PURPURA (ATTP): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST. |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | ATTP: 1) CABLIVI WAS PREVIOUSLY INITIATED AS PART OF AN FDA APPROVED TREATMENT REGIMEN IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY IN AN INPATIENT SETTING, AND 2) HAS NOT EXPERIENCED MORE THAN TWO RECURRENCES OF ATTP WHILE ON CABLIVI THERAPY (I.E., NEW DROP IN PLATELET COUNT REQUIRING REPEAT PLASMA EXCHANGE DURING 30 DAYS POST-PLASMA EXCHANGE THERAPY [PEX] AND UP TO 28 DAYS OF EXTENDED THERAPY). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# CAPMATINIB

## Products Affected

- TABRECTA

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

# CARGLUMIC ACID

## Products Affected

- *carglumic acid*

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

# CERITINIB

## Products Affected

- ZYKADIA

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

# CERTOLIZUMAB PEGOL

### Products Affected

- CIMZIA POWDER FOR RECONST
- CIMZIA SUBCUTANEOUS SYRINGE KIT 400 MG/2 ML (200 MG/ML X 2)

| 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, SCALP, 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, 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. 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, ORENCIA, OTEZLA. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, SKYRIZI, TREMFYA, OTEZLA. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ. CD: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ IR, ORENCIA, RINVOQ. INITIAL FOR RA, PSA, PSO, AS, CD, PJIA: TRIAL OF OR CONTRAINDICATION TO THE STEP AGENTS IS NOT REQUIRED IF THE PATIENT IS PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT. INITIAL/RENEWAL FOR PSA, PSO, AS, CD, NR-AXSPA, PJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR SAME INDICATION. RENEWAL FOR RA, PSA, AS, PSO, NR-AXSPA, PJIA: CONTINUES TO BENEFIT FROM MEDICATION. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# CETUXIMAB

## Products Affected

- ERBITUX

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

# CLADRIBINE

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 48 WEEKS. |
| **Other Criteria** | RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): 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 SELFJECT SUBCUTANEOUS PEN INJECTOR 40 UNIT/0.5 ML, 80 UNIT/ML
- CORTROPHIN GEL INJECTION
- CORTROPHIN GEL SUBCUTANEOUS SYRINGE 40 UNIT/0.5 ML, 80 UNIT/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | INITIAL: NOT APPROVED FOR DIAGNOSTIC PURPOSES. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MULTIPLE SCLEROSIS (MS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST/IMMUNOLOGIST, OPHTHALMOLOGIST, PULMONOLOGIST OR NEPHROLOGIST. |
| **Coverage Duration** | INFANTILE SPASMS AND MS: 28 DAYS. ALL OTHER FDA APPROVED INDICATIONS: INITIAL/RENEWAL: 12 MONTHS. |
| **Other Criteria** | INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS: TRIAL OF OR CONTRAINDICATION TO INTRAVENOUS (IV) CORTICOSTEROIDS. RENEWAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: DEMONSTRATED CLINICAL BENEFIT WHILE ON THERAPY AS INDICATED BY SYMPTOM RESOLUTION AND/OR NORMALIZATION OF LABORATORY TESTS. PART B BEFORE PART D STEP THERAPY, APPLIES ONLY TO BENEFICIARIES IN AN MA-PD PLAN. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | Yes |

# CRIZOTINIB

## 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 PELLET 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

## Products Affected

- TAFINLAR ORAL CAPSULE

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

# DABRAFENIB SUSPENSION

## Products Affected

- TAFINLAR ORAL TABLET FOR SUSPENSION

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

# DACOMITINIB

## Products Affected

- VIZIMPRO

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

# DALFAMPRIDINE

## Products Affected

- *dalfampridine*

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

# DARATUMUMAB

## Products Affected

- DARZALEX

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

# DARATUMUMAB-HYALURONIDASE-FIHJ

## Products Affected

- DARZALEX FASPRO

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

# DAROLUTAMIDE

## Products Affected

- NUBEQA

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

# DASATINIB

## Products Affected

- *dasatinib 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 DASATINIB 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 |

# DATOPOTAMAB DERUXTECAN-DLNK

## Products Affected

- DATROWAY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **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*

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

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

# DEFERIPRONE

## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | TRANSFUSIONAL IRON OVERLOAD: RENEWAL: SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | TRANSFUSIONAL IRON OVERLOAD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |
| **Other Criteria** | INITIAL: TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES: 1) TRIAL OF, CONTRAINDICATION, INTOLERABLE TOXICITIES, OR CLINICALLY SIGNIFICANT ADVERSE EFFECTS TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE, OR 2) CURRENT CHELATION THERAPY (I.E., FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE) IS INADEQUATE. TRANSFUSIONAL IRON OVERLOAD DUE TO SICKLE CELL DISEASE OR OTHER ANEMIAS: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# DENOSUMAB-XGEVA

## Products Affected

- XGEVA

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

# DEUTETRABENAZINE

### Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR TITRATION KT(WK1-4)

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

# DICLOFENAC TOPICAL GEL

## Products Affected

- *diclofenac sodium topical gel 3 %*

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

# DICLOFENAC TOPICAL SOLUTION

## Products Affected

- *diclofenac sodium topical solution in metered-dose pump*

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

# DIMETHYL FUMARATE

## Products Affected

- *dimethyl fumarate oral capsule,delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*

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

# DIROXIMEL FUMARATE

## Products Affected

- VUMERITY

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

# DOSTARLIMAB-GXLY

## Products Affected

- JEMPERLI

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

# DRONABINOL 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 PEN
- DUPIXENT SYRINGE

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

| PA Criteria | Criteria Details |
|---|---|
| **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 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. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (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. 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). EOSINOPHILIC COPD: 1) USED IN COMBINATION WITH A LAMA/LABA/ICS, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |

| PA Criteria | Criteria Details |
|---|---|
| | MOLECULES FOR EOSINOPHILIC COPD. 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 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, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. PN: IMPROVEMENT OR REDUCTION OF PRURITIS OR PRURIGINOUS LESIONS. EOSINOPHILIC COPD: 1) USED IN COMBINATION WITH A LAMA/LABA/ICS, 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR EOSINOPHILIC COPD, AND 3) CLINICAL RESPONSE AS EVIDENCED BY (A) REDUCTION IN COPD EXACERBATIONS FROM BASELINE, (B) REDUCTION IN SEVERITY OR FREQUENCY OF COPD-RELATED SYMPTOMS, OR (C) INCREASE IN FEV1 OF AT LEAST 5 PERCENT FROM PRETREATMENT BASELINE. |
| **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 |

# EFLAPEGRASTIM-XNST

## Products Affected

- ROLVEDON

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

# 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 |

# ELAFIBRANOR

## Products Affected

- IQIRVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE LEVEL, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES OR OTHER PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210, IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE (OBTAINED BY LIVER BIOPSY) OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS |
| **Other Criteria** | PBC: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC, 2) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE AFTER TREATMENT WITH URSODIOL MONOTHERAPY FOR AT LEAST 1 YEAR, OR USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL, AND 3) DOES NOT HAVE DECOMPENSATED CIRRHOSIS (CHILD-PUGH B OR C). RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# ELAGOLIX

## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

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

# ELAPEGADEMASE-LVLR

## Products Affected

- REVCOVI

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

# ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: LIFETIME. |
| **Other Criteria** | CF: RENEWAL: IMPROVEMENT IN CLINICAL STATUS. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ELIGLUSTAT

## Products Affected

- CERDELGA

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

# ELRANATAMAB-BCMM

## Products Affected

- ELREXFIO 44 MG/1.1 ML VIAL INNER, SUV, P/F
- ELREXFIO SUBCUTANEOUS SOLUTION 40 MG/ML

| 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

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS AND A PRIOR BLEEDING EVENT. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| **Coverage Duration** | ITP: INITIAL: 6 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO. |
| **Other Criteria** | INITIAL: ITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, OR HAD AN INSUFFICIENT RESPONSE TO SPLENECTOMY, AND 2) NO CONCURRENT USE WITH OTHER THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS) OR SPLEEN TYROSINE KINASE (SYK) INHIBITOR. ALL INDICATIONS: APPROVAL FOR PROMACTA ORAL SUSPENSION PACKETS REQUIRES A TRIAL OF PROMACTA TABLET OR PATIENT IS UNABLE TOLERATE TABLET FORMULATION. RENEWAL: ITP: 1) IMPROVEMENT IN PLATELET COUNTS 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 - 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 X 10^9/L FROM AT LEAST 2 SEPARATE LABS IN THE LAST 3 MONTHS, OR 2) PLATELET COUNT IS LESS THAN 50 X 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: 6 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO. |
| **Other Criteria** | INITIAL: ITP: 1) TRIAL OF OR CONTRAINDICATION TO ONE CORTICOSTEROID OR IMMUNOGLOBULIN, 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 |

# 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

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

# ENTRECTINIB

## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

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

# ENTRECTINIB PELLETS

## Products Affected

- ROZLYTREK ORAL PELLETS IN 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 |

# EPCORITAMAB-BYSP

## Products Affected

- EPKINLY

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

# EPOETIN ALFA-EPBX

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL 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. |

| 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 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

| 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, MDD: 1) NON-PSYCHOTIC, UNIPOLAR DEPRESSION, AND 2) NO ACTIVE SUBSTANCE ABUSE. RENEWAL: TRD, MDD: DEMONSTRATED CLINICAL BENEFIT (IMPROVEMENT IN DEPRESSION) COMPARED TO BASELINE. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# ETANERCEPT

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, SCALP, 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. 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 FOR PSO. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO |
| | CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# EVEROLIMUS-AFINITOR

## Products Affected

- *everolimus (antineoplastic) 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 (antineoplastic) oral tablet for suspension*

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

# FECAL MICROBIOTA CAPSULE

## Products Affected

- VOWST

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

# FEDRATINIB

## Products Affected

- INREBIC

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

# FENFLURAMINE

## Products Affected

- FINTEPLA

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

# FENTANYL CITRATE

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | CANCER RELATED PAIN: 1) CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO AT LEAST ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR PATIENT HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES. |
| **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 |

# FILGRASTIM-AAFI

## Products Affected

- NIVESTYM

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

# FILGRASTIM-SNDZ

## Products Affected

- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NIVESTYM, WHERE INDICATIONS ALIGN |
| **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*

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

# FOSCARBIDOPA-FOSLEVODOPA

## Products Affected

- VYALEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST. |
| **Coverage Duration** | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | PD: INITIAL: 1) RESPONSIVE TO LEVODOPA, 2) CURRENT REGIMEN INCLUDES AT LEAST 400 MG/DAY OF LEVODOPA, AND 3) MOTOR SYMPTOMS ARE CURRENTLY UNCONTROLLED (DEFINED AS AN AVERAGE OFF TIME OF AT LEAST 2.5 HOURS/DAY OVER 3 CONSECUTIVE DAYS WITH A MINIMUM OF 2 HOURS EACH DAY). RENEWAL: IMPROVEMENT IN MOTOR SYMPTOMS WHILE ON THERAPY. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# FOSTAMATINIB

## Products Affected

- TAVALISSE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | CHRONIC IMMUNE THROMBOCYTOPENIA (CITP): INITIAL: 1) PLATELET COUNT OF LESS THAN 30 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS, OR 2) PLATELET COUNT OF LESS THAN 50 X 10^9/L FROM AT LEAST 2 SEPARATE LAB TESTS IN THE LAST 3 MONTHS AND A PRIOR BLEEDING EVENT. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CITP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | CITP: INITIAL: NO CONCURRENT USE WITH THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAS). RENEWAL: 1) IMPROVEMENT IN PLATELET COUNTS FROM BASELINE OR REDUCTION IN BLEEDING EVENTS, AND 2) NO CONCURRENT USE WITH TPO-RAS. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# FREMANEZUMAB-VFRM

## Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| **Other Criteria** | MIGRAINE PREVENTION: INITIAL: 1) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREVENTIVE MIGRAINE TREATMENTS: DIVALPROEX SODIUM, TOPIRAMATE, PROPRANOLOL, TIMOLOL, AND 2) NO CONCURRENT USE 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 ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

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

# GALCANEZUMAB-GNLM

### Products Affected

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

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

# GANAXOLONE

## Products Affected

- ZTALMY

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

# GEFITINIB

## Products Affected

- *gefitinib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | METASTATIC 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 subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml*

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

# GLECAPREVIR/PIBRENTASVIR

## Products Affected

- MAVYRET ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HCV RNA LEVEL WITHIN PAST 6 MONTHS |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| **Other Criteria** | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) ONE OF THE FOLLOWING, WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE: (A) SHORT TRIAL OF A PREFERRED FORMULARY AGENT: HARVONI OR EPCLUSA, OR (B) CONTRAINDICATION TO BOTH OF THE PREFERRED FORMULARY AGENTS: HARVONI AND EPCLUSA, 3) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: CARBAMAZEPINE, RIFAMPIN, ETHINYL ESTRADIOL-CONTAINING MEDICATION, ATAZANAVIR, DARUNAVIR, LOPINAVIR, RITONAVIR, EFAVIRENZ, ATORVASTATIN, LOVASTATIN, SIMVASTATIN, ROSUVASTATIN AT DOSES GREATER THAN 10MG, CYCLOSPORINE AT DOSES GREATER THAN 100MG PER DAY, EPCLUSA, HARVONI, VOSEVI, OR ZEPATIER, AND 4) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# GLP1-DULAGLUTIDE

## Products Affected

- TRULICITY

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

# GLP1-SEMAGLUTIDE

## Products Affected

- OZEMPIC
- RYBELSUS

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

# GLP1-TIRZEPATIDE

## Products Affected

- MOUNJARO

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

# GLYCEROL PHENYLBUTYRATE

## Products Affected

- RAVICTI

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

# GOSERELIN

## Products Affected

- ZOLADEX

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

# GUSELKUMAB

## Products Affected

- TREMFYA
- TREMFYA PEN SUBCUTANEOUS PEN INJECTOR 200 MG/2 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, SCALP, 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. ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# HIGH CONCENTRATION ORAL OPIOID SOLUTIONS

## Products Affected

- *morphine concentrate oral solution*
- *oxycodone oral concentrate*

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

# HIGH RISK DRUGS IN THE ELDERLY - CARBINOXAMINE

## Products Affected

- *carbinoxamine maleate oral liquid*

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

# HIGH RISK DRUGS IN THE ELDERLY - CYPROHEPTADINE

## Products Affected

- *cyproheptadine*

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

# HIGH RISK DRUGS IN THE ELDERLY - BUTALBITAL-CONTAINING AGENTS

### Products Affected

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

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

# HIGH RISK DRUGS IN THE ELDERLY - CLEMASTINE

## Products Affected

- *clemastine oral tablet*

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

# HIGH RISK DRUGS IN THE ELDERLY - CONJUGATED ESTROGEN

## Products Affected

- PREMARIN ORAL

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

# HIGH RISK DRUGS IN THE ELDERLY - DIPYRIDAMOLE

## Products Affected

- *dipyridamole oral*

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

# HIGH RISK DRUGS IN THE ELDERLY - DISOPYRAMIDE

## Products Affected

- *disopyramide phosphate oral capsule*

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

# HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL

## Products Affected

- *dotti*
- *estradiol oral*
- *estradiol transdermal patch semiweekly*
- *estradiol transdermal patch weekly*
- *lyllana*

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

# HIGH RISK DRUGS IN THE ELDERLY - ESTRADIOL-NORETHINDRONE

## Products Affected

- *amabelz*
- *estradiol-norethindrone acet*
- *mimvey*

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

# HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-BAZEDOXIFENE

## Products Affected

- DUAVEE

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

# HIGH RISK DRUGS IN THE ELDERLY - ESTROGEN-MEDROXYPROGESTERONE

### Products Affected

- PREMPHASE
- PREMPRO

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

# HIGH RISK DRUGS IN THE ELDERLY - GLYBURIDE FORMULATIONS

## Products Affected

- *glyburide*
- *glyburide micronized*
- *glyburide-metformin*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | TYPE 2 DIABETES MELLITUS (DM): 1) TRIAL OF OR CONTRAINDICATION TO GLIMEPIRIDE OR GLIPIZIDE, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# HIGH RISK DRUGS IN THE ELDERLY - KETOROLAC

## Products Affected

- *ketorolac oral*

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

# HIGH RISK DRUGS IN THE ELDERLY - NORETHINDRONE-ESTRADIOL

## Products Affected

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

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

# HIGH RISK DRUGS IN THE ELDERLY - PHENOBARBITAL

## Products Affected

- *phenobarbital*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | EPILEPSY/SEIZURES: PATIENTS WHO ARE NEWLY PRESCRIBED PHENOBARBITAL: 1) HAS NOT RESPONDED TO AT LEAST ONE ANTICONVULSANT, OR 2) PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# HIGH RISK DRUGS IN THE ELDERLY - PROMETHAZINE

## Products Affected

- *promethazine injection solution 25 mg/ml*
- *promethazine oral*
- *promethazine rectal*
- *promethegan*

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

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

# HIGH RISK DRUGS IN THE ELDERLY - SCOPOLAMINE

## Products Affected

- *scopolamine base*

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

# HIGH RISK DRUGS IN THE ELDERLY - SKELETAL MUSCLE RELAXANTS

## Products Affected

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

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

# HIGH RISK DRUGS IN THE ELDERLY-DIPHENOXYLATE-ATROPINE

## Products Affected

- *diphenoxylate-atropine*

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

# HIGH RISK DRUGS IN THE ELDERLY-INDOMETHACIN

## Products Affected

- *indomethacin oral capsule*

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

# HIGH RISK DRUGS IN THE ELDERLY-MEGESTROL

## Products Affected

- *megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml)*
- *megestrol oral tablet*

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

# HIGH RISK DRUGS IN THE ELDERLY-PAROXETINE

## Products Affected

- *paroxetine hcl oral suspension*
- *paroxetine hcl oral tablet*

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

# IBRUTINIB

## Products Affected

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

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

# IBUPROFEN-FAMOTIDINE

## Products Affected

- *ibuprofen-famotidine*

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

# ICATIBANT

## Products Affected

- *icatibant*
- *sajazir*

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

# IDELALISIB

## Products Affected

- ZYDELIG

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

# IMATINIB

## Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

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

# IMATINIB SOLUTION

## Products Affected

- IMKELDI

| 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. ALL INDICATIONS: UNABLE TO SWALLOW GENERIC IMATINIB TABLETS. |
| **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 |

# INAVOLISIB

## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 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 |

# 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, SCALP, OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, 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 PSA. PSO: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER |

| PA Criteria | Criteria Details |
|---|---|
| | SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# INFLIXIMAB-ABDA

## Products Affected

- RENFLEXIS

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, 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 PSA. PSO: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER |

| PA Criteria | Criteria Details |
|---|---|
| | SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# INFLIXIMAB-AXXQ

## Products Affected

- AVSOLA

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, 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 PSA. PSO: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER |

| PA Criteria | Criteria Details |
|---|---|
| | SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# INFLIXIMAB-DYYB

## Products Affected

- INFLECTRA

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PSA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, 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 PSA. PSO: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, STELARA/SELARSDI/YESINTEK, SKYRIZI, TREMFYA, OTEZLA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: COSENTYX, ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: STELARA/SELARSDI/YESINTEK, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER |

| PA Criteria | Criteria Details |
|---|---|
| | SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. MODERATE TO SEVERE CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# INFLIXIMAB-DYYB - SQ

## Products Affected

- ZYMFENTRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: 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: UC: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: STELARA/SELARSDI/YESINTEK, XELJANZ, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, TREMFYA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR UC. CD: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: STELARA/SELARSDI/YESINTEK, HUMIRA/CYLTEZO/YUFLYMA, RINVOQ, SKYRIZI, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. RENEWAL: UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# INSULIN SUPPLY BVD PA

### Products Affected

- 1ST TIER UNIFINE PENTP 5MM 31G
- 1ST TIER UNIFINE PNTIP 4MM 32G
- 1ST TIER UNIFINE PNTIP 6MM 31G
- 1ST TIER UNIFINE PNTIP 8MM 31G STRL,SINGLE-USE,SHRT
- 1ST TIER UNIFINE PNTP 29GX1/2"
- 1ST TIER UNIFINE PNTP 31GX3/16
- 1ST TIER UNIFINE PNTP 32GX5/32
- ABOUTTIME PEN NEEDLE
- ADVOCATE INS 0.3 ML 30GX5/16"
- ADVOCATE INS 0.3 ML 31GX5/16"
- ADVOCATE INS 0.5 ML 30GX5/16"
- ADVOCATE INS 0.5 ML 31GX5/16"
- ADVOCATE INS 1 ML 31GX5/16"
- ADVOCATE INS SYR 0.3 ML 29GX1/2
- ADVOCATE INS SYR 0.5 ML 29GX1/2
- ADVOCATE INS SYR 1 ML 29GX1/2"
- ADVOCATE INS SYR 1 ML 30GX5/16
- ADVOCATE PEN NDL 12.7MM 29G
- ADVOCATE PEN NEEDLE 32G 4MM
- ADVOCATE PEN NEEDLE 4MM 33G
- ADVOCATE PEN NEEDLES 5MM 31G
- ADVOCATE PEN NEEDLES 8MM 31G
- ALCOHOL 70% SWABS
- ALCOHOL PADS
- ALCOHOL PREP SWABS
- ALCOHOL WIPES
- AQINJECT PEN NEEDLE 31G 5MM
- AQINJECT PEN NEEDLE 32G 4MM
- ASSURE ID DUO PRO NDL 31G 5MM
- ASSURE ID DUO-SHIELD 30GX3/16"
- ASSURE ID DUO-SHIELD 30GX5/16"
- ASSURE ID INSULIN SAFETY SYRINGE 1 ML 29 GAUGE X 1/2"
- ASSURE ID PEN NEEDLE 30GX3/16"
- ASSURE ID PEN NEEDLE 30GX5/16"
- ASSURE ID PEN NEEDLE 31GX3/16"
- ASSURE ID PRO PEN NDL 30G 5MM
- ASSURE ID SYR 0.5 ML 29GX1/2" (RX)
- ASSURE ID SYR 0.5 ML 31GX15/64"
- ASSURE ID SYR 1 ML 31GX15/64"
- AUTOSHIELD DUO PEN NDL 30G 5MM
- BD AUTOSHIELD DUO NDL 5MMX30G
- BD ECLIPSE 30GX1/2" SYRINGE
- BD ECLIPSE NEEDLE 30GX1/2" (OTC)
- BD INS SYR 0.3 ML 8MMX31G(1/2)
- BD INS SYR UF 0.3 ML 12.7MMX30G
- BD INS SYR UF 0.5 ML 12.7MMX30G NOT FOR RETAIL SALE
- BD INS SYRN UF 1 ML 12.7MMX30G NOT FOR RETAIL SALE
- BD INS SYRNG UF 0.3 ML 8MMX31G
- BD INS SYRNG UF 0.5 ML 8MMX31G
- BD INSULIN SYR 1 ML 25GX1"
- BD INSULIN SYR 1 ML 25GX5/8"
- BD INSULIN SYR 1 ML 26GX1/2"
- BD INSULIN SYR 1 ML 27GX12.7MM
- BD INSULIN SYR 1 ML 27GX5/8" MICRO-FINE
- BD INSULIN SYRINGE SLIP TIP
- BD INSULIN SYRINGE U-500
- BD LUER-LOK SYRINGE 1 ML
- BD NANO 2 GEN PEN NDL 32G 4MM
- BD SAFETGLD INS 0.3 ML 29G 13MM
- BD SAFETGLD INS 0.5 ML 13MMX29G
- BD SAFETYGLD INS 0.3 ML 31G 8MM
- BD SAFETYGLD INS 0.5 ML 30G 8MM
- BD SAFETYGLD INS 1 ML 29G 13MM
- BD SAFETYGLID INS 1 ML 6MMX31G
- BD SAFETYGLIDE SYRINGE 27GX5/8
- BD SAFTYGLD INS 0.3 ML 6MMX31G
- BD SAFTYGLD INS 0.5 ML 29G 13MM
- BD SAFTYGLD INS 0.5 ML 6MMX31G
- BD SINGLE USE SWAB
- BD UF MICRO PEN NEEDLE 6MMX32G
- BD UF MINI PEN NEEDLE 5MMX31G
- BD UF NANO PEN NEEDLE 4MMX32G
- BD UF ORIG PEN NDL 12.7MMX29G
- BD UF SHORT PEN NEEDLE 8MMX31G
- BD VEO INS 0.3 ML 6MMX31G (1/2)
- BD VEO INS SYRING 1 ML 6MMX31G
- BD VEO INS SYRN 0.3 ML 6MMX31G
- BD VEO INS SYRN 0.5 ML 6MMX31G
- BORDERED GAUZE 2"X2"
- CAREFINE PEN NEEDLE 12.7MM 29G
- CAREFINE PEN NEEDLE 4MM 32G

- CAREFINE PEN NEEDLE 5MM 32G
- CAREFINE PEN NEEDLE 6MM 31G
- CAREFINE PEN NEEDLE 8MM 30G
- CAREFINE PEN NEEDLES 6MM 32G
- CAREFINE PEN NEEDLES 8MM 31G
- CARETOUCH ALCOHOL 70% PREP PAD
- CARETOUCH PEN NEEDLE 29G 12MM
- CARETOUCH PEN NEEDLE 31GX1/4"
- CARETOUCH PEN NEEDLE 31GX3/16"
- CARETOUCH PEN NEEDLE 31GX5/16"
- CARETOUCH PEN NEEDLE 32GX3/16"
- CARETOUCH PEN NEEDLE 32GX5/32"
- CARETOUCH SYR 0.3 ML 31GX5/16"
- CARETOUCH SYR 0.5 ML 30GX5/16"
- CARETOUCH SYR 0.5 ML 31GX5/16"
- CARETOUCH SYR 1 ML 28GX5/16"
- CARETOUCH SYR 1 ML 29GX5/16"
- CARETOUCH SYR 1 ML 30GX5/16"
- CARETOUCH SYR 1 ML 31GX5/16"
- CLICKFINE 31G X 5/16" NEEDLES 8MM, UNIVERSAL
- CLICKFINE PEN NEEDLE 32GX5/32" 32GX4MM, STERILE
- CLICKFINE UNIVERSAL 31G X 1/4" 6MM, STORE BRAND
- COMFORT EZ 0.3 ML 31G 15/64"
- COMFORT EZ 0.5 ML 31G 15/64"
- COMFORT EZ INS 0.3 ML 30GX1/2"
- COMFORT EZ INS 0.3 ML 30GX5/16"
- COMFORT EZ INS 1 ML 31G 15/64"
- COMFORT EZ INS 1 ML 31GX5/16"
- COMFORT EZ INSULIN SYR 0.3 ML
- COMFORT EZ INSULIN SYR 0.5 ML
- COMFORT EZ PEN NEEDLE 12MM 29G
- COMFORT EZ PEN NEEDLES 4MM 32G SINGLE USE, MICRO
- COMFORT EZ PEN NEEDLES 4MM 33G
- COMFORT EZ PEN NEEDLES 5MM 31G MINI
- COMFORT EZ PEN NEEDLES 5MM 32G SINGLE USE,MINI,HRI
- COMFORT EZ PEN NEEDLES 5MM 33G
- COMFORT EZ PEN NEEDLES 6MM 31G
- COMFORT EZ PEN NEEDLES 6MM 32G
- COMFORT EZ PEN NEEDLES 6MM 33G
- COMFORT EZ PEN NEEDLES 8MM 31G SHORT
- COMFORT EZ PEN NEEDLES 8MM 32G
- COMFORT EZ PEN NEEDLES 8MM 33G
- COMFORT EZ PRO PEN NDL 30G 8MM
- COMFORT EZ PRO PEN NDL 31G 4MM
- COMFORT EZ PRO PEN NDL 31G 5MM
- COMFORT EZ SYR 0.3 ML 29GX1/2"
- COMFORT EZ SYR 0.5 ML 28GX1/2"
- COMFORT EZ SYR 0.5 ML 29GX1/2"
- COMFORT EZ SYR 0.5 ML 30GX1/2"
- COMFORT EZ SYR 1 ML 28GX1/2"
- COMFORT EZ SYR 1 ML 29GX1/2"
- COMFORT EZ SYR 1 ML 30GX1/2"
- COMFORT EZ SYR 1 ML 30GX5/16"
- COMFORT POINT PEN NDL 31GX1/3"
- COMFORT POINT PEN NDL 31GX1/6"
- COMFORT TOUCH PEN NDL 31G 4MM
- COMFORT TOUCH PEN NDL 31G 5MM
- COMFORT TOUCH PEN NDL 31G 6MM
- COMFORT TOUCH PEN NDL 31G 8MM
- COMFORT TOUCH PEN NDL 32G 4MM
- COMFORT TOUCH PEN NDL 32G 5MM
- COMFORT TOUCH PEN NDL 32G 6MM
- COMFORT TOUCH PEN NDL 32G 8MM
- COMFORT TOUCH PEN NDL 33G 4MM
- COMFORT TOUCH PEN NDL 33G 6MM
- COMFORT TOUCH PEN NDL 33GX5MM
- CURAD GAUZE PADS 2" X 2"
- CURITY ALCOHOL PREPS 2 PLY,MEDIUM
- CURITY GAUZE SPONGES (12 PLY)-200/BAG
- CURITY GUAZE PADS 1'S(12 PLY)
- DERMACEA 2"X2" GAUZE 12 PLY, USP TYPE VII
- DERMACEA GAUZE 2"X2" SPONGE 8 PLY
- DERMACEA NON-WOVEN 2"X2" SPNGE
- DROPLET 0.3 ML 29G 12.7MM(1/2)
- DROPLET 0.3 ML 30G 12.7MM(1/2)
- DROPLET 0.5 ML 29GX12.5MM(1/2)
- DROPLET 0.5 ML 30GX12.5MM(1/2)
- DROPLET INS 0.3 ML 29GX12.5MM
- DROPLET INS 0.3 ML 30G 8MM(1/2)
- DROPLET INS 0.3 ML 30GX12.5MM
- DROPLET INS 0.3 ML 31G 6MM(1/2)
- DROPLET INS 0.3 ML 31G 8MM(1/2)

- DROPLET INS 0.5 ML 29G 12.7MM
- DROPLET INS 0.5 ML 30G 12.7MM
- DROPLET INS 0.5 ML 30GX6MM(1/2)
- DROPLET INS 0.5 ML 30GX8MM(1/2)
- DROPLET INS 0.5 ML 31GX6MM(1/2)
- DROPLET INS 0.5 ML 31GX8MM(1/2)
- DROPLET INS SYR 0.3 ML 30GX6MM
- DROPLET INS SYR 0.3 ML 30GX8MM
- DROPLET INS SYR 0.3 ML 31GX6MM
- DROPLET INS SYR 0.3 ML 31GX8MM
- DROPLET INS SYR 0.5 ML 30G 8MM
- DROPLET INS SYR 0.5 ML 31G 6MM
- DROPLET INS SYR 0.5 ML 31G 8MM
- DROPLET INS SYR 1 ML 29GX12.5MM
- DROPLET INS SYR 1 ML 30GX12.5MM
- DROPLET INS SYR 1 ML 30GX6MM
- DROPLET INS SYR 1 ML 30GX8MM
- DROPLET INS SYR 1 ML 31G 6MM
- DROPLET INS SYR 1 ML 31GX6MM
- DROPLET INS SYR 1 ML 31GX8MM
- DROPLET MICRON 34G X 9/64"
- DROPLET PEN NEEDLE 29G 10MM
- DROPLET PEN NEEDLE 29G 12MM
- DROPLET PEN NEEDLE 30G 8MM
- DROPLET PEN NEEDLE 31G 5MM
- DROPLET PEN NEEDLE 31G 6MM
- DROPLET PEN NEEDLE 31G 8MM
- DROPLET PEN NEEDLE 32G 4MM
- DROPLET PEN NEEDLE 32G 5MM
- DROPLET PEN NEEDLE 32G 6MM
- DROPLET PEN NEEDLE 32G 8MM
- DROPSAFE ALCOHOL 70% PREP PADS
- DROPSAFE INS SYR 0.3 ML 31G 6MM
- DROPSAFE INS SYR 0.3 ML 31G 8MM
- DROPSAFE INS SYR 0.5 ML 31G 6MM
- DROPSAFE INS SYR 0.5 ML 31G 8MM
- DROPSAFE INSUL SYR 1 ML 31G 6MM
- DROPSAFE INSUL SYR 1 ML 31G 8MM
- DROPSAFE INSULN 1 ML 29G 12.5MM
- DROPSAFE PEN NEEDLE 31GX1/4"
- DROPSAFE PEN NEEDLE 31GX3/16"
- DROPSAFE PEN NEEDLE 31GX5/16"
- DRUG MART ULTRA COMFORT SYR
- EASY CMFT SFTY PEN NDL 31G 5MM
- EASY CMFT SFTY PEN NDL 31G 6MM
- EASY CMFT SFTY PEN NDL 32G 4MM
- EASY COMFORT 0.3 ML 31G 1/2"
- EASY COMFORT 0.3 ML 31G 5/16"
- EASY COMFORT 0.3 ML SYRINGE
- EASY COMFORT 0.5 ML 30GX1/2"
- EASY COMFORT 0.5 ML 31GX5/16"
- EASY COMFORT 0.5 ML 32GX5/16"
- EASY COMFORT 0.5 ML SYRINGE
- EASY COMFORT 1 ML 31GX5/16"
- EASY COMFORT 1 ML 32GX5/16"
- EASY COMFORT ALCOHOL 70% PAD
- EASY COMFORT INSULIN 1 ML SYR
- EASY COMFORT PEN NDL 31GX1/4"
- EASY COMFORT PEN NDL 31GX3/16"
- EASY COMFORT PEN NDL 31GX5/16"
- EASY COMFORT PEN NDL 32GX5/32"
- EASY COMFORT PEN NDL 33G 4MM
- EASY COMFORT PEN NDL 33G 5MM
- EASY COMFORT PEN NDL 33G 6MM
- EASY COMFORT SYR 0.5 ML 29G 8MM
- EASY COMFORT SYR 1 ML 29G 8MM
- EASY COMFORT SYR 1 ML 30GX1/2"
- EASY GLIDE INS 0.3 ML 31GX6MM
- EASY GLIDE INS 0.5 ML 31GX6MM
- EASY GLIDE INS 1 ML 31GX6MM
- EASY GLIDE PEN NEEDLE 4MM 33G
- EASY TOUCH 0.3 ML SYR 30GX1/2"
- EASY TOUCH 0.5 ML SYR 27GX1/2"
- EASY TOUCH 0.5 ML SYR 29GX1/2"
- EASY TOUCH 0.5 ML SYR 30GX1/2"
- EASY TOUCH 0.5 ML SYR 30GX5/16
- EASY TOUCH 1 ML SYR 27GX1/2"
- EASY TOUCH 1 ML SYR 29GX1/2"
- EASY TOUCH 1 ML SYR 30GX1/2"
- EASY TOUCH ALCOHOL 70% PADS GAMMA-STERILIZED
- EASY TOUCH FLIPLOK 1 ML 27GX0.5
- EASY TOUCH INSULIN 1 ML 29GX1/2
- EASY TOUCH INSULIN 1 ML 30GX1/2
- EASY TOUCH INSULIN SYR 0.3 ML
- EASY TOUCH INSULIN SYR 0.5 ML
- EASY TOUCH INSULIN SYR 1 ML
- EASY TOUCH INSULIN SYR 1 ML RETRACTABLE
- EASY TOUCH INSULN 1 ML 29GX1/2"
- EASY TOUCH INSULN 1 ML 30GX1/2"
- EASY TOUCH INSULN 1 ML 30GX5/16
- EASY TOUCH INSULN 1 ML 31GX5/16
- EASY TOUCH LUER LOK INSUL 1 ML

- EASY TOUCH PEN NEEDLE 29GX1/2"
- EASY TOUCH PEN NEEDLE 30GX5/16
- EASY TOUCH PEN NEEDLE 31GX1/4"
- EASY TOUCH PEN NEEDLE 31GX3/16
- EASY TOUCH PEN NEEDLE 31GX5/16
- EASY TOUCH PEN NEEDLE 32GX1/4"
- EASY TOUCH PEN NEEDLE 32GX3/16
- EASY TOUCH PEN NEEDLE 32GX5/32
- EASY TOUCH SAF PEN NDL 29G 5MM
- EASY TOUCH SAF PEN NDL 29G 8MM
- EASY TOUCH SAF PEN NDL 30G 5MM
- EASY TOUCH SAF PEN NDL 30G 8MM
- EASY TOUCH SYR 0.5 ML 28G 12.7MM
- EASY TOUCH SYR 0.5 ML 29G 12.7MM
- EASY TOUCH SYR 1 ML 27G 16MM
- EASY TOUCH SYR 1 ML 28G 12.7MM
- EASY TOUCH SYR 1 ML 29G 12.7MM
- EASY TOUCH UNI-SLIP SYR 1 ML
- EASYTOUCH SAF PEN NDL 30G 6MM
- EMBRACE PEN NEEDLE 29G 12MM
- EMBRACE PEN NEEDLE 30G 5MM
- EMBRACE PEN NEEDLE 30G 8MM
- EMBRACE PEN NEEDLE 31G 5MM
- EMBRACE PEN NEEDLE 31G 6MM
- EMBRACE PEN NEEDLE 31G 8MM
- EMBRACE PEN NEEDLE 32G 4MM
- EQL INSULIN 0.3 ML SYRINGE SHORT NEEDLE
- EQL INSULIN 0.5 ML SYRINGE SHORT NEEDLE
- EQL INSULIN 1 ML SYRINGE SHORT NEEDLE
- FIFTY50 INS SYR 1 ML 31GX5/16" SHORT NEEDLE (OTC)
- FIFTY50 PEN 31G X 3/16" NEEDLE (OTC)
- FP INSULIN 1 ML SYRINGE
- FREESTYLE PREC 0.5 ML 30GX5/16
- FREESTYLE PREC 0.5 ML 31GX5/16
- FREESTYLE PREC 1 ML 30GX5/16"
- FREESTYLE PREC 1 ML 31GX5/16"
- GAUZE PAD TOPICAL BANDAGE 2 X 2 "
- GNP ULT C 0.3 ML 29GX1/2" (1/2) 1/2 UNIT
- GNP ULTRA COMFORT 0.5 ML SYR
- GNP ULTRA COMFORT 1 ML SYRINGE
- GNP ULTRA COMFORT 3/10 ML SYR
- HEALTHWISE INS 0.3 ML 30GX5/16"
- HEALTHWISE INS 0.3 ML 31GX5/16"
- HEALTHWISE INS 0.5 ML 30GX5/16"
- HEALTHWISE INS 0.5 ML 31GX5/16"
- HEALTHWISE INS 1 ML 30GX5/16"
- HEALTHWISE INS 1 ML 31GX5/16"
- HEALTHWISE PEN NEEDLE 31G 5MM
- HEALTHWISE PEN NEEDLE 31G 8MM
- HEALTHWISE PEN NEEDLE 32G 4MM
- HEALTHY ACCENTS PENTIP 4MM 32G
- HEALTHY ACCENTS PENTIP 5MM 31G
- HEALTHY ACCENTS PENTIP 6MM 31G
- HEALTHY ACCENTS PENTIP 8MM 31G
- HEALTHY ACCENTS PENTP 12MM 29G
- HEB INCONTROL ALCOHOL 70% PADS
- INCONTROL PEN NEEDLE 12MM 29G
- INCONTROL PEN NEEDLE 4MM 32G
- INCONTROL PEN NEEDLE 5MM 31G
- INCONTROL PEN NEEDLE 6MM 31G
- INCONTROL PEN NEEDLE 8MM 31G
- INSULIN SYR 0.3 ML 31GX1/4(1/2)
- INSULIN SYRIN 0.5 ML 28GX1/2" (OTC)
- INSULIN SYRIN 0.5 ML 29GX1/2" (OTC)
- INSULIN SYRIN 0.5 ML 30GX1/2" (RX)
- INSULIN SYRIN 0.5 ML 30GX5/16" SHORT NEEDLE (OTC)
- INSULIN SYRING 0.5 ML 27G 1/2" OUTER
- INSULIN SYRINGE 0.3 ML
- INSULIN SYRINGE 0.3 ML 31GX1/4
- INSULIN SYRINGE 0.5 ML
- INSULIN SYRINGE 0.5 ML 31GX1/4
- INSULIN SYRINGE 1 ML
- INSULIN SYRINGE 1 ML 27G 1/2" INNER
- INSULIN SYRINGE 1 ML 27G 16MM
- INSULIN SYRINGE 1 ML 28GX1/2" (OTC)
- INSULIN SYRINGE 1 ML 30GX1/2" (RX)
- INSULIN SYRINGE 1 ML 30GX5/16" SHORT NEEDLE (OTC)
- INSULIN SYRINGE 1 ML 31GX1/4"
- INSULIN SYRINGE-NEEDLE U-100 SYRINGE 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE
- INSUPEN 30G ULTRAFIN NEEDLE

- INSUPEN 31G ULTRAFIN NEEDLE
- INSUPEN 32G 6MM PEN NEEDLE
- INSUPEN 32G 8MM PEN NEEDLE
- INSUPEN PEN NEEDLE 29GX12MM
- INSUPEN PEN NEEDLE 31GX3/16"
- INSUPEN PEN NEEDLE 32GX4MM
- INSUPEN PEN NEEDLE 33GX4MM
- IV ANTISEPTIC WIPES
- KENDALL ALCOHOL 70% PREP PAD
- LISCO SPONGES 100/BAG
- LITE TOUCH 31GX1/4" PEN NEEDLE
- LITE TOUCH INSULIN 0.5 ML SYR
- LITE TOUCH INSULIN 1 ML SYR
- LITE TOUCH INSULIN SYR 1 ML
- LITE TOUCH PEN NEEDLE 29G
- LITE TOUCH PEN NEEDLE 31G
- LITETOUCH INS 0.3 ML 29GX1/2"
- LITETOUCH INS 0.3 ML 30GX5/16"
- LITETOUCH INS 0.3 ML 31GX5/16"
- LITETOUCH INS 0.5 ML 31GX5/16"
- LITETOUCH SYR 0.5 ML 28GX1/2"
- LITETOUCH SYR 0.5 ML 29GX1/2"
- LITETOUCH SYR 0.5 ML 30GX5/16"
- LITETOUCH SYRIN 1 ML 28GX1/2"
- LITETOUCH SYRIN 1 ML 29GX1/2"
- LITETOUCH SYRIN 1 ML 30GX5/16"
- MAGELLAN INSUL SYRINGE 0.3 ML
- MAGELLAN INSUL SYRINGE 0.5 ML
- MAGELLAN INSULIN SYR 0.3 ML
- MAGELLAN INSULIN SYR 0.5 ML
- MAGELLAN INSULIN SYRINGE 1 ML
- MAXI-COMFORT INS 0.5 ML 28G
- MAXI-COMFORT INS 1 ML 28GX1/2"
- MAXICOMFORT II PEN NDL 31GX6MM
- MAXICOMFORT INS 0.5 ML 27GX1/2"
- MAXICOMFORT INS 1 ML 27GX1/2"
- MAXICOMFORT PEN NDL 29G X 5MM
- MAXICOMFORT PEN NDL 29G X 8MM
- MICRODOT PEN NEEDLE 31GX6MM
- MICRODOT PEN NEEDLE 32GX4MM
- MICRODOT PEN NEEDLE 33GX4MM
- MICRODOT READYGARD NDL 31G 5MM OUTER
- MINI PEN NEEDLE 32G 4MM
- MINI PEN NEEDLE 32G 5MM
- MINI PEN NEEDLE 32G 6MM
- MINI PEN NEEDLE 32G 8MM
- MINI PEN NEEDLE 33G 4MM
- MINI PEN NEEDLE 33G 5MM
- MINI PEN NEEDLE 33G 6MM
- MINI ULTRA-THIN II PEN NDL 31G STERILE
- MONOJECT 0.5 ML SYRN 28GX1/2"
- MONOJECT 1 ML SYRN 27X1/2"
- MONOJECT 1 ML SYRN 28GX1/2" (OTC)
- MONOJECT INSUL SYR U100 (OTC)
- MONOJECT INSUL SYR U100 .5ML,29GX1/2" (OTC)
- MONOJECT INSUL SYR U100 0.5 ML CONVERTS TO 29G (OTC)
- MONOJECT INSUL SYR U100 1 ML
- MONOJECT INSUL SYR U100 1 ML 3'S, 29GX1/2" (OTC)
- MONOJECT INSUL SYR U100 1 ML W/O NEEDLE (OTC)
- MONOJECT INSULIN SYR 0.3 ML
- MONOJECT INSULIN SYR 0.3 ML (OTC)
- MONOJECT INSULIN SYR 0.5 ML
- MONOJECT INSULIN SYR 0.5 ML (OTC)
- MONOJECT INSULIN SYR 1 ML 3'S (OTC)
- MONOJECT INSULIN SYR U-100
- MONOJECT SYRINGE 0.3 ML
- MONOJECT SYRINGE 0.5 ML
- MONOJECT SYRINGE 1 ML
- NANO 2 GEN PEN NEEDLE 32G 4MM
- NOVOFINE 30
- NOVOFINE 32G NEEDLES
- NOVOFINE PLUS PEN NDL 32GX1/6"
- NOVOTWIST NEEDLE 32G 5MM
- PC UNIFINE PENTIPS 8MM NEEDLE SHORT
- PEN NEEDLE 30G 5MM OUTER
- PEN NEEDLE 30G 8MM INNER
- PEN NEEDLE 30G X 5/16"
- PEN NEEDLE, DIABETIC NEEDLE 29 GAUGE X 1/2"
- PEN NEEDLES 12MM 29G 29GX12MM,STRL
- PEN NEEDLES 4MM 32G
- PEN NEEDLES 6MM 31G 31GX6MM, STRL
- PEN NEEDLES 8MM 31G 31GX8MM,STRL,SHORT (OTC)

- PENTIPS PEN NEEDLE 29G 1/2"
- PENTIPS PEN NEEDLE 31G 1/4"
- PENTIPS PEN NEEDLE 31GX3/16" MINI, 5MM
- PENTIPS PEN NEEDLE 31GX5/16" SHORT, 8MM
- PENTIPS PEN NEEDLE 32G 1/4"
- PENTIPS PEN NEEDLE 32GX5/32" 4MM
- PIP PEN NEEDLE 31G X 5MM
- PIP PEN NEEDLE 32G X 4MM
- PREVENT PEN NEEDLE 31GX1/4"
- PREVENT PEN NEEDLE 31GX5/16"
- PRO COMFORT 0.5 ML 30GX1/2"
- PRO COMFORT 0.5 ML 30GX5/16"
- PRO COMFORT 0.5 ML 31GX5/16"
- PRO COMFORT 1 ML 30GX1/2"
- PRO COMFORT 1 ML 30GX5/16"
- PRO COMFORT 1 ML 31GX5/16"
- PRO COMFORT ALCOHOL 70% PADS
- PRO COMFORT PEN NDL 31GX5/16"
- PRO COMFORT PEN NDL 32G X 1/4"
- PRO COMFORT PEN NDL 4MM 32G
- PRO COMFORT PEN NDL 5MM 32G
- PRODIGY INS SYR 1 ML 28GX1/2"
- PRODIGY SYRNG 0.5 ML 31GX5/16"
- PRODIGY SYRNGE 0.3 ML 31GX5/16"
- PURE CMFT SFTY PEN NDL 31G 5MM
- PURE CMFT SFTY PEN NDL 31G 6MM
- PURE CMFT SFTY PEN NDL 32G 4MM
- PURE COMFORT ALCOHOL 70% PADS
- PURE COMFORT PEN NDL 32G 4MM
- PURE COMFORT PEN NDL 32G 5MM
- PURE COMFORT PEN NDL 32G 6MM
- PURE COMFORT PEN NDL 32G 8MM
- RAYA SURE PEN NEEDLE 29G 12MM
- RAYA SURE PEN NEEDLE 31G 4MM
- RAYA SURE PEN NEEDLE 31G 5MM
- RAYA SURE PEN NEEDLE 31G 6MM
- RELI-ON INSULIN 0.5 ML SYR
- RELI-ON INSULIN 1 ML SYR
- RELION INS SYR 0.3 ML 31GX6MM
- RELION INS SYR 0.5 ML 31GX6MM
- RELION INS SYR 1 ML 31GX15/64"
- RELION MINI PEN 31G X 1/4" NDL
- SAFESNAP INS SYR UNITS-100 0.3 ML 30GX5/16",10X10
- SAFESNAP INS SYR UNITS-100 0.5 ML 29GX1/2",10X10
- SAFESNAP INS SYR UNITS-100 0.5 ML 30GX5/16",10X10
- SAFESNAP INS SYR UNITS-100 1 ML 28GX1/2",10X10
- SAFESNAP INS SYR UNITS-100 1 ML 29GX1/2",10X10
- SAFETY PEN NEEDLE 31G 4MM
- SAFETY PEN NEEDLE 5MM X 31G
- SAFETY SYRINGE 0.5 ML 30G 1/2"
- SECURESAFE PEN NDL 30GX5/16" OUTER
- SECURESAFE SYR 0.5 ML 29G 1/2" OUTER
- SECURESAFE SYRNG 1 ML 29G 1/2" OUTER
- SKY SAFETY PEN NEEDLE 30G 5MM
- SKY SAFETY PEN NEEDLE 30G 8MM
- SM ULT CFT 0.3 ML 31GX5/16(1/2)
- STERILE PADS 2" X 2"
- SURE CMFT SFTY PEN NDL 31G 6MM
- SURE CMFT SFTY PEN NDL 32G 4MM
- SURE COMFORT 0.5 ML SYRINGE
- SURE COMFORT 1 ML SYRINGE
- SURE COMFORT 3/10 ML SYRINGE
- SURE COMFORT 3/10 ML SYRINGE INSULIN SYRINGE
- SURE COMFORT 30G PEN NEEDLE
- SURE COMFORT ALCOHOL PREP PADS
- SURE COMFORT INS 0.3 ML 31GX1/4
- SURE COMFORT INS 0.5 ML 31GX1/4
- SURE COMFORT INS 1 ML 31GX1/4"
- SURE COMFORT PEN NDL 29GX1/2" 12.7MM
- SURE COMFORT PEN NDL 31G 5MM
- SURE COMFORT PEN NDL 31G 8MM
- SURE COMFORT PEN NDL 32G 4MM
- SURE COMFORT PEN NDL 32G 6MM
- SURE-FINE PEN NEEDLES 12.7MM
- SURE-FINE PEN NEEDLES 5MM
- SURE-FINE PEN NEEDLES 8MM
- SURE-JECT INSU SYR U100 0.3 ML
- SURE-JECT INSU SYR U100 0.5 ML
- SURE-JECT INSU SYR U100 1 ML
- SURE-JECT INSUL SYR U100 1 ML
- SURE-JECT INSULIN SYRINGE 1 ML
- SURE-PREP ALCOHOL PREP PADS

- TECHLITE 0.3 ML 29GX12MM (1/2)
- TECHLITE 0.3 ML 30GX8MM (1/2)
- TECHLITE 0.3 ML 31GX6MM (1/2)
- TECHLITE 0.3 ML 31GX8MM (1/2)
- TECHLITE 0.5 ML 30GX12MM (1/2)
- TECHLITE 0.5 ML 30GX8MM (1/2)
- TECHLITE 0.5 ML 31GX6MM (1/2)
- TECHLITE 0.5 ML 31GX8MM (1/2)
- TECHLITE INS SYR 1 ML 29GX12MM
- TECHLITE INS SYR 1 ML 30GX12MM
- TECHLITE INS SYR 1 ML 30GX8MM
- TECHLITE INS SYR 1 ML 31GX6MM
- TECHLITE INS SYR 1 ML 31GX8MM
- TECHLITE PEN NEEDLE 29GX1/2"
- TECHLITE PEN NEEDLE 29GX3/8"
- TECHLITE PEN NEEDLE 31GX1/4"
- TECHLITE PEN NEEDLE 31GX3/16"
- TECHLITE PEN NEEDLE 31GX5/16"
- TECHLITE PEN NEEDLE 32GX1/4"
- TECHLITE PEN NEEDLE 32GX5/16"
- TECHLITE PEN NEEDLE 32GX5/32"
- TECHLITE PLUS PEN NDL 32G 4MM
- TERUMO INS SYRINGE U100-1 ML
- TERUMO INS SYRINGE U100-1/2 ML
- TERUMO INS SYRINGE U100-1/3 ML
- TERUMO INS SYRNG U100-1/2 ML
- THINPRO INS SYRIN U100-0.3 ML
- THINPRO INS SYRIN U100-0.5 ML
- THINPRO INS SYRIN U100-1 ML
- TOPCARE CLICKFINE 31G X 1/4"
- TOPCARE CLICKFINE 31G X 5/16"
- TOPCARE ULTRA COMFORT SYRINGE
- TRUE CMFRT PRO 0.5 ML 30G 5/16"
- TRUE CMFRT PRO 0.5 ML 31G 5/16"
- TRUE CMFRT PRO 0.5 ML 32G 5/16"
- TRUE CMFT SFTY PEN NDL 31G 5MM
- TRUE CMFT SFTY PEN NDL 31G 6MM
- TRUE CMFT SFTY PEN NDL 32G 4MM
- TRUE COMFORT 0.5 ML 30G 1/2"
- TRUE COMFORT 0.5 ML 30G 5/16"
- TRUE COMFORT 0.5 ML 31G 5/16"
- TRUE COMFORT 0.5 ML 31GX5/16"
- TRUE COMFORT 1 ML 31GX5/16"
- TRUE COMFORT ALCOHOL 70% PADS
- TRUE COMFORT PEN NDL 31G 8MM
- TRUE COMFORT PEN NDL 31GX5MM
- TRUE COMFORT PEN NDL 31GX6MM
- TRUE COMFORT PEN NDL 32G 5MM
- TRUE COMFORT PEN NDL 32G 6MM
- TRUE COMFORT PEN NDL 32GX4MM
- TRUE COMFORT PEN NDL 33G 4MM
- TRUE COMFORT PEN NDL 33G 5MM
- TRUE COMFORT PEN NDL 33G 6MM
- TRUE COMFORT PRO 1 ML 30G 1/2"
- TRUE COMFORT PRO 1 ML 30G 5/16"
- TRUE COMFORT PRO 1 ML 31G 5/16"
- TRUE COMFORT PRO 1 ML 32G 5/16"
- TRUE COMFORT PRO ALCOHOL PADS
- TRUE COMFORT SFTY 1 ML 30G 1/2"
- TRUE COMFRT PRO 0.5 ML 30G 1/2"
- TRUE COMFRT SFTY 1 ML 30G 5/16"
- TRUE COMFRT SFTY 1 ML 31G 5/16"
- TRUE COMFRT SFTY 1 ML 32G 5/16"
- TRUEPLUS PEN NEEDLE 29GX1/2"
- TRUEPLUS PEN NEEDLE 31G X 1/4"
- TRUEPLUS PEN NEEDLE 31GX3/16"
- TRUEPLUS PEN NEEDLE 31GX5/16"
- TRUEPLUS PEN NEEDLE 32GX5/32"
- TRUEPLUS SYR 0.3 ML 29GX1/2"
- TRUEPLUS SYR 0.3 ML 30GX5/16"
- TRUEPLUS SYR 0.3 ML 31GX5/16"
- TRUEPLUS SYR 0.5 ML 28GX1/2"
- TRUEPLUS SYR 0.5 ML 29GX1/2"
- TRUEPLUS SYR 0.5 ML 30GX5/16"
- TRUEPLUS SYR 0.5 ML 31GX5/16"
- TRUEPLUS SYR 1 ML 28GX1/2"
- TRUEPLUS SYR 1 ML 29GX1/2"
- TRUEPLUS SYR 1 ML 30GX5/16"
- TRUEPLUS SYR 1 ML 31GX5/16"
- ULTICAR INS 0.3 ML 31GX1/4(1/2)
- ULTICARE INS 1 ML 31GX1/4"
- ULTICARE INS SYR 0.3 ML 30G 8MM
- ULTICARE INS SYR 0.3 ML 31G 6MM
- ULTICARE INS SYR 0.3 ML 31G 8MM
- ULTICARE INS SYR 0.5 ML 31G 6MM
- ULTICARE INS SYR 0.5 ML 31G 8MM (OTC)
- ULTICARE INS SYR 1 ML 30GX1/2"
- ULTICARE PEN NEEDLE 31GX3/16"
- ULTICARE PEN NEEDLE 6MM 31G
- ULTICARE PEN NEEDLE 8MM 31G
- ULTICARE PEN NEEDLES 12MM 29G
- ULTICARE PEN NEEDLES 4MM 32G MICRO, 32GX4MM

- ULTICARE PEN NEEDLES 6MM 32G
- ULTICARE SAFE PEN NDL 30G 8MM
- ULTICARE SAFE PEN NDL 5MM 30G
- ULTICARE SYR 0.3 ML 29G 12.7MM
- ULTICARE SYR 0.3 ML 30GX1/2"
- ULTICARE SYR 0.3 ML 31GX5/16" SHORT NDL
- ULTICARE SYR 0.5 ML 30GX1/2"
- ULTICARE SYR 0.5 ML 31GX5/16" SHORT NDL
- ULTICARE SYR 1 ML 31GX5/16"
- ULTIGUARD SAFE 1 ML 30G 12.7MM
- ULTIGUARD SAFE0.3 ML 30G 12.7MM
- ULTIGUARD SAFE0.5 ML 30G 12.7MM
- ULTIGUARD SAFEPACK 1 ML 31G 8MM
- ULTIGUARD SAFEPACK 29G 12.7MM
- ULTIGUARD SAFEPACK 31G 5MM
- ULTIGUARD SAFEPACK 31G 6MM
- ULTIGUARD SAFEPACK 31G 8MM
- ULTIGUARD SAFEPACK 32G 4MM
- ULTIGUARD SAFEPACK 32G 6MM
- ULTIGUARD SAFEPK 0.3 ML 31G 8MM
- ULTIGUARD SAFEPK 0.5 ML 31G 8MM
- ULTILET ALCOHOL STERL SWAB
- ULTILET INSULIN SYRINGE 0.3 ML
- ULTILET INSULIN SYRINGE 0.5 ML
- ULTILET INSULIN SYRINGE 1 ML
- ULTILET PEN NEEDLE
- ULTILET PEN NEEDLE 4MM 32G
- ULTRA COMFORT 0.3 ML SYRINGE
- ULTRA COMFORT 0.5 ML 28GX1/2" CONVERTS TO 29G
- ULTRA COMFORT 0.5 ML 29GX1/2"
- ULTRA COMFORT 0.5 ML SYRINGE
- ULTRA COMFORT 1 ML 31GX5/16"
- ULTRA COMFORT 1 ML SYRINGE
- ULTRA FLO 0.3 ML 30G 1/2" (1/2)
- ULTRA FLO 0.3 ML 30G 5/16"(1/2)
- ULTRA FLO 0.3 ML 31G 5/16"(1/2)
- ULTRA FLO PEN NEEDLE 31G 5MM
- ULTRA FLO PEN NEEDLE 31G 8MM
- ULTRA FLO PEN NEEDLE 32G 4MM
- ULTRA FLO PEN NEEDLE 33G 4MM
- ULTRA FLO PEN NEEDLES 12MM 29G
- ULTRA FLO SYR 0.3 ML 29GX1/2"
- ULTRA FLO SYR 0.3 ML 30G 5/16"
- ULTRA FLO SYR 0.3 ML 31G 5/16"
- ULTRA FLO SYR 0.5 ML 29G 1/2"
- ULTRA THIN PEN NDL 32G X 4MM
- ULTRA-FINE 0.3 ML 30G 12.7MM
- ULTRA-FINE 0.3 ML 31G 6MM (1/2)
- ULTRA-FINE 0.3 ML 31G 8MM (1/2)
- ULTRA-FINE 0.5 ML 30G 12.7MM
- ULTRA-FINE INS SYR 1 ML 31G 8MM
- ULTRA-FINE PEN NDL 29G 12.7MM
- ULTRA-FINE PEN NEEDLE 32G 6MM
- ULTRA-FINE SYR 0.5 ML 31G 8MM
- ULTRA-FINE SYR 1 ML 30G 12.7MM
- ULTRA-THIN II 1 ML 31GX5/16"
- ULTRA-THIN II INS 0.3 ML 30G
- ULTRA-THIN II INS 0.3 ML 31G
- ULTRA-THIN II INS 0.5 ML 29G
- ULTRA-THIN II INS 0.5 ML 30G
- ULTRA-THIN II INS 0.5 ML 31G
- ULTRA-THIN II INS SYR 1 ML 29G
- ULTRA-THIN II INS SYR 1 ML 30G
- ULTRA-THIN II PEN NDL 29GX1/2"
- ULTRA-THIN II PEN NDL 31GX5/16
- ULTRACARE INS 0.3 ML 30GX5/16"
- ULTRACARE INS 0.3 ML 31GX5/16"
- ULTRACARE INS 0.5 ML 30GX1/2"
- ULTRACARE INS 0.5 ML 30GX5/16"
- ULTRACARE INS 0.5 ML 31GX5/16"
- ULTRACARE INS 1 ML 30G X 5/16"
- ULTRACARE INS 1 ML 30GX1/2"
- ULTRACARE INS 1 ML 31G X 5/16"
- ULTRACARE PEN NEEDLE 31GX1/4"
- ULTRACARE PEN NEEDLE 31GX3/16"
- ULTRACARE PEN NEEDLE 31GX5/16"
- ULTRACARE PEN NEEDLE 32GX1/4"
- ULTRACARE PEN NEEDLE 32GX3/16"
- ULTRACARE PEN NEEDLE 32GX5/32"
- ULTRACARE PEN NEEDLE 33GX5/32"
- UNIFINE OTC PEN NEEDLE 31G 5MM
- UNIFINE OTC PEN NEEDLE 32G 4MM
- UNIFINE PEN NEEDLE 32G 4MM
- UNIFINE PENTIPS 12MM 29G 29GX12MM, STRL
- UNIFINE PENTIPS 31GX3/16" 31GX5MM,STRL,MINI
- UNIFINE PENTIPS 32GX1/4"
- UNIFINE PENTIPS 32GX5/32" 32GX4MM, STRL, NANO
- UNIFINE PENTIPS 33GX5/32"

- UNIFINE PENTIPS 6MM 31G
- UNIFINE PENTIPS MAX 30GX3/16"
- UNIFINE PENTIPS NEEDLES 29G
- UNIFINE PENTIPS PLUS 29GX1/2" 12MM
- UNIFINE PENTIPS PLUS 30GX3/16"
- UNIFINE PENTIPS PLUS 31GX1/4" ULTRA SHORT, 6MM
- UNIFINE PENTIPS PLUS 31GX3/16" MINI
- UNIFINE PENTIPS PLUS 31GX5/16" SHORT
- UNIFINE PENTIPS PLUS 32GX5/32"
- UNIFINE PENTIPS PLUS 33GX5/32"
- UNIFINE PROTECT 30G 5MM
- UNIFINE PROTECT 30G 8MM
- UNIFINE PROTECT 32G 4MM
- UNIFINE SAFECONTROL 30G 5MM
- UNIFINE SAFECONTROL 30G 8MM
- UNIFINE SAFECONTROL 31G 5MM
- UNIFINE SAFECONTROL 31G 6MM
- UNIFINE SAFECONTROL 31G 8MM
- UNIFINE SAFECONTROL 32G 4MM
- UNIFINE ULTRA PEN NDL 31G 5MM
- UNIFINE ULTRA PEN NDL 31G 6MM
- UNIFINE ULTRA PEN NDL 31G 8MM
- UNIFINE ULTRA PEN NDL 32G 4MM
- VANISHPOINT 0.5 ML 30GX1/2" SY OUTER
- VANISHPOINT INS 1 ML 30GX3/16"
- VANISHPOINT U-100 29X1/2 SYR
- VERIFINE INS SYR 1 ML 29G 1/2"
- VERIFINE PEN NEEDLE 29G 12MM
- VERIFINE PEN NEEDLE 31G 5MM
- VERIFINE PEN NEEDLE 31G X 6MM
- VERIFINE PEN NEEDLE 31G X 8MM
- VERIFINE PEN NEEDLE 32G 6MM
- VERIFINE PEN NEEDLE 32G X 4MM
- VERIFINE PEN NEEDLE 32G X 5MM
- VERIFINE PLUS PEN NDL 31G 5MM
- VERIFINE PLUS PEN NDL 31G 8MM
- VERIFINE PLUS PEN NDL 32G 4MM
- VERIFINE PLUS PEN NDL 32G 4MM-SHARPS CONTAINER
- VERIFINE SYRING 0.5 ML 29G 1/2"
- VERIFINE SYRING 1 ML 31G 5/16"
- VERIFINE SYRNG 0.3 ML 31G 5/16"
- VERIFINE SYRNG 0.5 ML 31G 5/16"
- VERSALON ALL PURPOSE SPONGE 25'S,N-STERILE,3PLY
- WEBCOL ALCOHOL PREPS 20'S,LARGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | LIFETIME |
| **Other Criteria** | ONLY COVERED UNDER PART D WHEN USED CONCURRENTLY WITH INSULIN. |

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

# INTERFERON FOR MS-AVONEX

### Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT
- AVONEX PEN 30 MCG/0.5 ML

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

# INTERFERON FOR MS-BETASERON

## Products Affected

- BETASERON SUBCUTANEOUS KIT

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

# INTERFERON FOR MS-PLEGRIDY

## Products Affected

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

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

# INTERFERON GAMMA-1B

## Products Affected

- ACTIMMUNE

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

# IPILIMUMAB

## Products Affected

- YERVOY

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

# ITRACONAZOLE SOLUTION

## Products Affected

- *itraconazole oral solution*

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

# IVACAFTOR

## Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT |
| **Coverage Duration** | INITIAL: 12 MONTHS. RENEWAL: LIFETIME |
| **Other Criteria** | CF: INITIAL: NOT HOMOZYGOUS FOR F508DEL MUTATION IN CFTR GENE. RENEWAL: IMPROVEMENT IN CLINICAL STATUS. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# IVOSIDENIB

## Products Affected

- TIBSOVO

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

# IXAZOMIB

## Products Affected

- NINLARO

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

# LANADELUMAB-FLYO

## Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION MG/ML)
- TAKHZYRO SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML (150

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING COMPLEMENT TESTING: C1INH PROTEIN LEVELS, C4 PROTEIN LEVELS, C1-INH FUNCTIONAL LEVELS, C1Q. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR PULMONOLOGIST. |
| **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 |

# LANREOTIDE

## Products Affected

- *lanreotide subcutaneous syringe 120 mg/0.5 ml*
- SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 60 MG/0.2 ML, 90 MG/0.3 ML

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

# LAPATINIB

## Products Affected

- *lapatinib*

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

# LAROTRECTINIB

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | 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 PELLETS IN PACKET
  33.75-150 MG, 45-200 MG
- HARVONI ORAL TABLET

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

# LENALIDOMIDE

## Products Affected

- *lenalidomide*

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

# LENVATINIB

## Products Affected

- LENVIMA

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

# LETERMOVIR

## Products Affected

- PREVYMIS ORAL PELLETS IN PACKET
- PREVYMIS ORAL TABLET

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

# LEUPROLIDE

## Products Affected

- *leuprolide subcutaneous kit*

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

# LEUPROLIDE DEPOT

## Products Affected

- *leuprolide (3 month)*

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

# LEUPROLIDE-ELIGARD

## Products Affected

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

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

# LEUPROLIDE-LUPRON DEPOT

### Products Affected

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

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

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

# LEUPROLIDE-LUPRON DEPOT-PED

## Products Affected

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

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

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

# LEVODOPA

## Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

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

# L-GLUTAMINE

## Products Affected

- *glutamine (sickle cell)*

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

# LIDOCAINE OINTMENT

## Products Affected

- *lidocaine topical ointment*

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

- *dermacinrx lidocan 5% patch outer*
- *lidocaine topical adhesive patch,medicated 5 %*
- *lidocan iii*
- 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** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# LIDOCAINE PRILOCAINE

## Products Affected

- *lidocaine-prilocaine topical cream*

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

# LIDOCAINE SOLUTION

## Products Affected

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

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

# LOMITAPIDE

## Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH): 1) DIAGNOSIS DETERMINED BY: (A) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, (B) DUTCH LIPID NETWORK CRITERIA SCORE OF AT LEAST 8, OR (C) CLINICAL DIAGNOSIS BASED ON A HISTORY OF AN UNTREATED LDL-C CONCENTRATION GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS, AND 2) LDL-C LEVEL OF AT LEAST 70MG/DL WHILE ON MAXIMALLY TOLERATED DRUG TREATMENT. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | HOFH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST. |
| **Coverage Duration** | 12 MONTHS |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | HOFH: 1) TRIAL OF REPATHA, UNLESS THE PATIENT HAS NON-FUNCTIONING LDL RECEPTORS, AND 2) ONE OF THE FOLLOWING: (A) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, (B) TAKING A MAXIMALLY TOLERATED DOSE OF ANY STATIN FOR A DURATION OF AT LEAST 8 WEEKS GIVEN THAT THE PATIENT CANNOT TOLERATE A HIGH-INTENSITY STATIN, (C) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), (D) STATIN INTOLERANCE, OR (E) TRIAL OF ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# LONCASTUXIMAB TESIRINE-LPYL

## Products Affected

- ZYNLONTA

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

# LORLATINIB

## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

# LOTILANER

## Products Affected

- XDEMVY

| 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 |

# LUMACAFTOR-IVACAFTOR

### Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: CYSTIC FIBROSIS (CF): CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CF. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CF EXPERT. |
| **Coverage Duration** | INITIAL: 6 MONTHS, RENEWAL: LIFETIME. |
| **Other Criteria** | CF: RENEWAL: IMPROVEMENT IN CLINICAL STATUS. |
| **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** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST OR NEPHROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | INITIAL: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF WRIST AND HAND. RENEWAL: IMPROVEMENT WHILE ON THERAPY (I.E., INCREASE IN HEIGHT OR INCREASE IN HEIGHT VELOCITY). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# MECHLORETHAMINE

## Products Affected

- VALCHLOR

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

# MEPOLIZUMAB

### Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL 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: 12 MO. CRSWNP: 6 MO. OTHERS: 12 MO. RENEWAL: CRSWNP, ASTHMA: 12 MO. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (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 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. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# METHYLNALTREXONE INJECTABLE

## Products Affected

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

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

# METHYLNALTREXONE ORAL

## Products Affected

- RELISTOR ORAL

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

# MIDOSTAURIN

## Products Affected

- RYDAPT

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

# MIFEPRISTONE

## Products Affected

- *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 GLUCOCORTICOIDS. RENEWAL: 1) CONTINUES TO HAVE IMPROVEMENT OF GLUCOSE TOLERANCE OR STABLE GLUCOSE TOLERANCE (E.G., REDUCED A1C, IMPROVED FASTING GLUCOSE, ETC.), 2) CONTINUES TO HAVE TOLERABILITY TO 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 |

# MIGALASTAT

## Products Affected

- GALAFOLD

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | FABRY DISEASE: INITIAL: 1) HAS AN AMENABLE GALACTOSIDASE ALPHA GENE (GLA) VARIANT BASED ON IN VITRO ASSAY DATA THAT IS INTERPRETED BY A CLINICAL GENETICS PROFESSIONAL AS PATHOGENIC OR LIKELY PATHOGENIC, AND 2) ONE OF THE FOLLOWING: (A) FEMALES: GLA GENE MUTATION VIA GENETIC TESTING, OR (B) MALES: ENZYME ASSAY INDICATING ALPHA GALACTOSIDASE A DEFICIENCY OR GLA GENE MUTATION VIA GENETIC TESTING. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS. |
| **Coverage Duration** | INITIAL: 6 MOS. RENEWAL: 12 MOS. |
| **Other Criteria** | FABRY DISEASE: INITIAL: NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NO CONCURRENT USE WITH ANOTHER FABRY DISEASE THERAPY. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# MIGLUSTAT

## Products Affected

- *miglustat*
- *yargesa*

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

# MILTEFOSINE

## Products Affected

- IMPAVIDO

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

# MIRDAMETINIB

## Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET FOR SUSPENSION

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

# MIRVETUXIMAB SORAVTANSINE-GYNX

## Products Affected

- ELAHERE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: AN OPHTHALMIC EXAM, INCLUDING VISUAL ACUITY AND SLIT LAMP EXAM, WILL BE COMPLETED PRIOR TO THE INITIATION OF THERAPY AND AT THE RECOMMENDED SCHEDULED INTERVALS. |
| **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 |

# MOMELOTINIB

## Products Affected

- OJJAARA

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

# MOSUNETUZUMAB-AXGB

## Products Affected

- LUNSUMIO

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

# NAFARELIN

## Products Affected

- SYNAREL

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

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

# NARCOLEPSY AGENTS

## Products Affected

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

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

# NAXITAMAB-GQGK

## Products Affected

- DANYELZA

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

# NEDOSIRAN

## Products Affected

- RIVFLOZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required 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 |

# NILOTINIB-DANZITEN

## Products Affected

- DANZITEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PREVIOUSLY TREATED PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): 1) PERFORMED MUTATIONAL ANALYSIS PRIOR TO INITIATION OF THERAPY, AND 2) THERAPY 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. |

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

# NIRAPARIB

## Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

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

# NIRAPARIB/ABIRATERONE

## Products Affected

- AKEEGA

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

# 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*
- ORFADIN ORAL SUSPENSION

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

# NIVOLUMAB

## Products Affected

- OPDIVO

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

# NIVOLUMAB-HYALURONIDASE-NVHY

## Products Affected

- OPDIVO QVANTIG

| 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 |

# 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 |

# OBETICHOLIC ACID

## Products Affected

- OCALIVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL/RENEWAL: COMPLETE BILIARY OBSTRUCTION. |
| **Required Medical Information** | PBC: INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES (AMA) OR PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210 IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS (BY LIVER BIOPSY). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS |
| **Other Criteria** | PBC: INITIAL: 1) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE AFTER TREATMENT WITH URSODIOL MONOTHERAPY FOR AT LEAST 1 YEAR, OR 2) USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# OCRELIZUMAB

## Products Affected

- OCREVUS

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

# OCRELIZUMAB-HYALURONIDASE-OCSQ

## Products Affected

- OCREVUS ZUNOVO

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

# OFATUMUMAB-SQ

## Products Affected

- KESIMPTA PEN

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

# OLANZAPINE/SAMIDORPHAN

## Products Affected

- LYBALVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | SCHIZOPHRENIA, BIPOLAR I: PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | SCHIZOPHRENIA: 1) 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 |

# OLAPARIB

## Products Affected

- LYNPARZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER: MEDICATION WILL BE USED AS MONOTHERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) 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 |

# 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/RENEWAL: ASTHMA 12 MO/12 MO, CSU 6 MO/12 MO, CRSWNP 6 MO/12 MO, FOOD ALLERGY 12 MO/24 MO |

| PA Criteria | Criteria Details |
|---|---|
| **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 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: MAINTAINED ON OR CONTRAINDICATION TO A SECOND GENERATION H1 ANTI-HISTAMINE. CRSWNP: 1) CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., |

| PA Criteria | Criteria Details |
|---|---|
| | JAK INHIBITOR, PDE-4 INHIBITOR) FOR AN AUTOIMMUNE INDICATION. ASTHMA: 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: 1) PERSISTENT IGE-MEDIATED FOOD ALLERGY, 2) CONCURRENT USE WITH AN ACTIVE PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTOR/INJECTION, AND 3) NO CONCURRENT USE WITH PEANUT-SPECIFIC IMMUNOTHERAPY. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# OPICAPONE

## Products Affected

- ONGENTYS

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

# OSIMERTINIB

## Products Affected

- TAGRISSO

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

# OXANDROLONE

## Products Affected

- *oxandrolone*

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

# PACRITINIB

## Products Affected

- VONJO

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

# PALBOCICLIB

## Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | ADVANCED OR METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO 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*

| 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-FPGK

## Products Affected

- STIMUFEND

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST. |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT NYVEPRIA, WHERE INDICATIONS ALIGN. |
| **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 |

# PEGFILGRASTIM-PBBK

## Products Affected

- FYLNETRA

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

# PEGINTERFERON ALFA-2A

## Products Affected

- PEGASYS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | HEPATITIS B: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, OR PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (E.G., HEPATOLOGIST). |
| **Coverage Duration** | HEP B/HEP C: 48 WEEKS. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# PEGVALIASE-PQPZ

## Products Affected

- PALYNZIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | PHENYLKETONURIA (PKU): INITIAL: NO CONCURRENT USE WITH KUVAN. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH KUVAN. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# PEGVISOMANT

## Products Affected

- SOMAVERT

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

# PEMBROLIZUMAB

## Products Affected

- KEYTRUDA

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

# PEMIGATINIB

## Products Affected

- PEMAZYRE

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

# PENICILLAMINE TABLET

## Products Affected

- *penicillamine oral tablet*

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

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

# PEXIDARTINIB

## Products Affected

- TURALIO

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

# PIMAVANSERIN

## Products Affected

- NUPLAZID

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

# PIRFENIDONE

## Products Affected

- *pirfenidone oral 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 |

# 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 SUSPENSION

## Products Affected

- *posaconazole oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | OPC: 3 MONTHS. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE, PROPHYLAXIS: 6 MONTHS. |
| **Other Criteria** | OROPHARYNGEAL CANDIDIASIS (OPC): TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE OR ITRACONAZOLE. PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: 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 |

# POSACONAZOLE TABLET

## Products Affected

- *posaconazole oral*

| 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 |

# POSACONAZOLE-POWDERMIX

## Products Affected

- NOXAFIL ORAL SUSP,DELAYED RELEASE FOR RECON

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

# PRALSETINIB

## Products Affected

- GAVRETO

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

# PRAMLINTIDE

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

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

# PYRIMETHAMINE

## Products Affected

- *pyrimethamine*

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

# QUININE

## Products Affected

- *quinine sulfate*

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

# QUIZARTINIB

## Products Affected

- VANFLYTA

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

# 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 ORAL CAPSULE 160 MG, 40 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 |

# 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** | INITIAL/RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND ONE OTHER MAINTENANCE MEDICATION, 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 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 |

# REVUMENIB

## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 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 |

# RIBOCICLIB

## Products Affected

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

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

# RIBOCICLIB-LETROZOLE

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | |
| **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** | 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. 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | CAPS, DIRA: LIFETIME. RP: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | CAPS: NO CONCURRENT USE WITH OTHER IL-1 INHIBITORS. 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 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 ODT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |
| **Other Criteria** | INITIAL: ACUTE MIGRAINE TREATMENT: 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. 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. 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. |

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

# RIOCIGUAT

## Products Affected

- ADEMPAS

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

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

| 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, SCALP, 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), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: 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 PSO. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# RISDIPLAM

## Products Affected

- EVRYSDI

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

# RITUXIMAB AND HYALURONIDASE HUMAN-SQ

## Products Affected

- RITUXAN HYCELA

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

# RITUXIMAB-ABBS

## Products Affected

- TRUXIMA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. 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/CYLTEZO/YUFLYMA, 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/CYLTEZO/YUFLYMA, 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/CYLTEZO/YUFLYMA, 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,soluble*
- *sapropterin oral tablet,soluble*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | INITIAL: 2 MONTHS, RENEWAL 12 MONTHS. |
| **Other Criteria** | HYPERPHENYLALANINEMIA (HPA): INITIAL: NO CONCURRENT USE WITH PALYNZIQ. RENEWAL: 1) CONTINUES TO BENEFIT FROM TREATMENT, AND 2) NO CONCURRENT USE WITH PALYNZIQ. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# SARGRAMOSTIM

## Products Affected

- LEUKINE INJECTION RECON SOLN

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

# SATRALIZUMAB-MWGE

## Products Affected

- ENSPRYNG

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

# SECUKINUMAB

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, 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: 12 MONTHS, ALL OTHER INDICATIONS: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **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 PSO. PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR NR-AXSPA. ERA: TRIAL OF OR CONTRAINDICATION TO ONE NSAID, SULFASALAZINE, OR METHOTREXATE. HS: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR HS. RENEWAL: PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL |
| | MOLECULES FOR NR-AXSPA. ERA, HS: CONTINUES TO BENEFIT FROM THE MEDICATION. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR NR-AXSPA. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. NR-AXSPA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR NR-AXSPA. 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 |

# SELADELPAR

## Products Affected

- LIVDELZI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PRIMARY BILIARY CHOLANGITIS (PBC): INITIAL: DIAGNOSIS CONFIRMED BY TWO OF THE FOLLOWING: 1) ELEVATED ALKALINE PHOSPHATASE LEVEL, 2) PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES OR OTHER PBC-SPECIFIC AUTOANTIBODIES, INCLUDING SP100 OR GP210, IF AMA IS NEGATIVE, OR 3) HISTOLOGIC EVIDENCE (OBTAINED BY LIVER BIOPSY) OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PBC: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS. |
| **Other Criteria** | PBC: INITIAL: 1) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC, 2) USED IN COMBINATION WITH URSODIOL IF INADEQUATE RESPONSE AFTER TREATMENT WITH URSODIOL MONOTHERAPY FOR AT LEAST 1 YEAR, OR USED AS MONOTHERAPY IF UNABLE TO TOLERATE URSODIOL, 3) DOES NOT HAVE DECOMPENSATED CIRRHOSIS (CHILD-PUGH B OR C), AND 4) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: OCALIVA, IQIRVO. STEP NOT APPLICABLE FOR WHOM ALLEVIATION OF PRURITUS IS A TREATMENT GOAL. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SECOND-LINE THERAPY FOR PBC. |
| **Indications** | All FDA-approved Indications. |

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

# SELEXIPAG

## Products Affected

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

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

# SELINEXOR

## Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (10 MG X 4), 40 MG/WEEK (20 MG X 2), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80MG TWICE WEEK (160 MG/WEEK)

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

# SELPERCATINIB

## Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- 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 (pulm.hypertension) oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: AGES 18 YEARS OR OLDER: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. AGES 1 TO 17 YEARS: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PAP GREATER THAN 20 MMHG, 2) PCWP OF 15 MMHG OR LESS, AND 3) PVR OF 3 WOOD UNITS OR GREATER. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS. |
| **Other Criteria** | PAH: INITIAL/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# SIPONIMOD

## Products Affected

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

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

# SODIUM PHENYLBUTYRATE TABLETS

## Products Affected

- *sodium phenylbutyrate oral tablet*

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

# SOFOSBUVIR/VELPATASVIR

## Products Affected

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

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

# SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

## Products Affected

- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HCV RNA LEVEL WITHIN PAST 6 MONTHS |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. |
| **Other Criteria** | 1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, CYCLOSPORINE, PITAVASTATIN, PRAVASTATIN (DOSES ABOVE 40MG), ROSUVASTATIN, METHOTREXATE, MITOXANTRONE, IMATINIB, IRINOTECAN, LAPATINIB, SULFASALAZINE, TOPOTECAN, OR HIV REGIMEN THAT CONTAINS EFAVIRENZ, ATAZANAVIR, LOPINAVIR, TIPRANAVIR/RITONAVIR, SOVALDI (AS A SINGLE AGENT), EPCLUSA, HARVONI, ZEPATIER, OR MAVYRET, AND 3) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# SOMATROPIN - NORDITROPIN

## Products Affected

- NORDITROPIN FLEXPRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES. |
| **Required Medical Information** | INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), TURNER SYNDROME (TS), NOONAN SYNDROME: HEIGHT AT LEAST 2 STANDARD DEVIATIONS 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 THE WRIST AND HAND. PWS: IMPROVEMENT IN BODY COMPOSITION. |

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

# SOMATROPIN - SEROSTIM

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES |
| **Required Medical Information** | INITIAL: HIV/WASTING: 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 |

# SONIDEGIB

## Products Affected

- ODOMZO

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

# SORAFENIB

## Products Affected

- *sorafenib*

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

# 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 |

# SOTORASIB

## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

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

# STIRIPENTOL

## Products Affected

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

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

# SUNITINIB

## Products Affected

- *sunitinib malate*

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

# TADALAFIL - ADCIRCA, ALYQ

## Products Affected

- *alyq*

| 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/RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA) OR ANY ORGANIC NITRATES IN ANY FORM, AND 2) NO CONCURRENT USE WITH GUANYLATE CYCLASE STIMULATORS. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TADALAFIL-CIALIS

## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

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

# TALAZOPARIB

## Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | ADVANCED OR METASTATIC BREAST CANCER: 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 |

# TASIMELTEON

## Products Affected

- HETLIOZ LQ
- *tasimelteon*

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

# TAZEMETOSTAT

## Products Affected

- TAZVERIK

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

# TEBENTAFUSP-TEBN

## Products Affected

- KIMMTRAK

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

# TECLISTAMAB-CQYV

## Products Affected

- TECVAYLI

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

# TEDUGLUTIDE

## Products Affected

- GATTEX 30-VIAL

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

# TELOTRISTAT

## Products Affected

- XERMELO

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

# TEPOTINIB

## Products Affected

- TEPMETKO

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

# TERIFLUNOMIDE

## Products Affected

- *teriflunomide*

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

# TERIPARATIDE

## Products Affected

- *teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/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 |

# TESAMORELIN

## Products Affected

- EGRIFTA SV

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

# TESTOSTERONE

## Products Affected

- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)*
- *testosterone transdermal solution in metered pump w/app*

| 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*

| 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*
- 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 |

# TEZACAFTOR/IVACAFTOR

## Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: LIFETIME |
| **Other Criteria** | CF: RENEWAL: IMPROVEMENT IN CLINICAL STATUS. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# THALIDOMIDE

## Products Affected

- THALOMID

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

# TILDRAKIZUMAB-ASMN

## Products Affected

- ILUMYA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, SCALP, OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. |
| **Other Criteria** | PSO: INITIAL: 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 PSO. RENEWAL: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. |
| **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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PJIA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ IR, RINVOQ, ORENCIA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. SJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TOCILIZUMAB SQ

## Products Affected

- ACTEMRA
- ACTEMRA ACTPEN

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PJIA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ IR, RINVOQ, ORENCIA, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. SJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. SSC-ILD: DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS). RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. SSC-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TOCILIZUMAB-AAZG

## Products Affected

- TYENNE
- TYENNE AUTOINJECTOR

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ, RINVOQ, ORENCIA. PJIA: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA/CYLTEZO/YUFLYMA, XELJANZ IR, ORENCIA, RINVOQ, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PJIA. SJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. SJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR SJIA. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TOFACITINIB

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS (PCJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF 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: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. PCJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PCJIA. AS: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. PCJIA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PCJIA. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TOLVAPTAN

## Products Affected

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLETS, SEQUENTIAL

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

# TOPICAL TRETINOIN

## Products Affected

- ALTRENO
- *tretinoin*

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

# 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 FOR RECONSTITUTION
- 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

## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

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

# TRAMETINIB SOLUTION

## Products Affected

- MEKINIST ORAL RECON SOLN

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

# TRASTUZUMAB HYALURONIDASE

## Products Affected

- HERCEPTIN HYLECTA

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

# TRASTUZUMAB-ANNS

## Products Affected

- KANJINTI

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

# TRASTUZUMAB-DKST

## Products Affected

- OGIVRI

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

# TRASTUZUMAB-DTTB

## Products Affected

- ONTRUZANT

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

# TRASTUZUMAB-PKRB

## Products Affected

- HERZUMA

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

# TRASTUZUMAB-QYYP

## Products Affected

- TRAZIMERA

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

# TRAZODONE

## Products Affected

- RALDESY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 MONTHS |
| **Other Criteria** | MAJOR DEPRESSIVE DISORDER (MDD): CONTRAINDICATION TO OR UNABLE TO SWALLOW TRAZODONE TABLETS. |
| **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 |

# TREPROSTINIL INHALED

## Products Affected

- TYVASO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH), PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| **Coverage Duration** | INITIAL: PAH: 12 MONTHS, PH-ILD: 6 MONTHS. RENEWAL: PAH, PH-ILD: 12 MONTHS. |
| **Other Criteria** | INITIAL: PAH: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR, 4) FORMULARY VERSION OF AN IV/SQ PROSTACYCLIN. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# TREPROSTINIL INJECTABLE

## Products Affected

- *treprostinil sodium*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: DIAGNOSIS CONFIRMED BY RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, 2) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND 3) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 2 WOOD UNITS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST. |
| **Coverage Duration** | INITIAL/RENEWAL: 12 MONTHS |
| **Other Criteria** | PAH: INITIAL: 1) CONTINUATION OF THERAPY FROM HOSPITAL DISCHARGE, 2) NEW START AND PHYSICIAN INDICATED PATIENT IS INTERMEDIATE OR HIGH RISK, OR 3) NEW START AND TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: (A) FORMULARY VERSION OF AN ORAL ENDOTHELIN RECEPTOR ANTAGONIST, (B) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR FOR PAH, (C) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

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

# TRIENTINE CAPSULE

## Products Affected

- *trientine oral capsule 250 mg*

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

# TRIFLURIDINE/TIPIRACIL

## Products Affected

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

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

# TRIPTORELIN-TRELSTAR

## Products Affected

- TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

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

# 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 |

# 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, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): 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. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF 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: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. PJIA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. AD: 1) INTRACTABLE PRURITUS 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: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. AS: 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 FOR AS. NR-AXSPA: 1) TRIAL OF OR CONTRAINDICATION TO AN NSAID, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR NR-AXSPA. 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: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. AS: 1) CONTINUES TO BENEFIT MEDICATION, AND 2) NO |

| PA Criteria | Criteria Details |
|---|---|
| | CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR AS. NR-AXSPA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR NR-AXSPA. PJIA: 1) CONTINUES TO BENEFIT FROM MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PJIA. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# USTEKINUMAB

## Products Affected

- STELARA

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# USTEKINUMAB IV

## Products Affected

- STELARA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | 2 MONTHS |
| **Other Criteria** | CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. 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 |

# USTEKINUMAB-AEKN IV

## Products Affected

- SELARSDI

| 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, SCALP OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# USTEKINUMAB-AEKN SQ

## Products Affected

- SELARSDI

| 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, SCALP OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# USTEKINUMAB-KFCE IV

## Products Affected

- YESINTEK

| 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, SCALP OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# USTEKINUMAB-KFCE SQ

## Products Affected

- YESINTEK

| 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, SCALP OR FACE. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL: PSA: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR PSA. 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 FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. RENEWAL: PSA: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSA. PSO: 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR PSO. CD: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR CD. UC: NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR UC. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# VALBENAZINE

## Products Affected

- INGREZZA
- INGREZZA INITIATION PK(TARDIV)
- INGREZZA SPRINKLE

| 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 |

# VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

## Products Affected

- ALYFTREK ORAL TABLET 10-50-125 MG, 4-20-50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT. |
| **Coverage Duration** | INITIAL: 6 MONTHS. RENEWAL: LIFETIME. |
| **Other Criteria** | CF: INITIAL: NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR. RENEWAL: 1) IMPROVEMENT IN CLINICAL STATUS, AND 2) NO CONCURRENT USE WITH ANOTHER CFTR MODULATOR. |
| **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, RIOCIGUAT, 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, RIOCIGUAT, OR PDE-5 INHIBITORS. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

# VIGABATRIN

## Products Affected

- *vigabatrin*
- *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 |

# VIMSELTINIB

## Products Affected

- ROMVIMZA

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

| 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 |

# ZANIDATAMAB-HRII

## Products Affected

- ZIIHERA

| 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 |

# 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 |

# ZENOCUTUZUMAB-ZBCO

## Products Affected

- BIZENGRI

| 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 |

# ZOLBETUXIMAB-CLZB

## Products Affected

- VYLOY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required 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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