



# **ATRIO Health Plans**

## **2021 Prior Authorization Requirements Special Needs Plans**

**Effective: 1/1/2021  
Last Updated: 10/5/2020**

# ABALOPARATIDE

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## Products Affected

- TYMLOS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# ABATACEPT IV

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## Products Affected

- ORENCIA (WITH MALTOSE)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS AND POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| Other Criteria               | INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND ENBREL. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ABATACEPT SQ

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## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS AND POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| Other Criteria               | INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND ENBREL. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ABEMACICLIB

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## Products Affected

- VERZENIO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | THE PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ABIRATERONE

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## Products Affected

- ZYTIGA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ABIRATERONE SUBMICRONIZED

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## Products Affected

- YONSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# ACALABRUTINIB

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## Products Affected

- CALQUENCE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# ADALIMUMAB

## Products Affected

- HUMIRA
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA(CF)
- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML

| PA Criteria                  | Criteria Details                  |
|------------------------------|-----------------------------------|
| Exclusion Criteria           | PA Criteria: Pending CMS Approval |
| Required Medical Information | PA Criteria: Pending CMS Approval |
| Age Restrictions             | PA Criteria: Pending CMS Approval |
| Prescriber Restrictions      | PA Criteria: Pending CMS Approval |
| Coverage Duration            | PA Criteria: Pending CMS Approval |
| Other Criteria               | PA Criteria: Pending CMS Approval |
| Indications                  | PA Criteria: Pending CMS Approval |
| Off Label Uses               | PA Criteria: Pending CMS Approval |

# AFATINIB DIMALEATE

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## Products Affected

- GILOTRIF

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# AGALSIDASE BETA

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## Products Affected

- FABRAZYME

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | FABRY DISEASE INITIAL: THE PATIENT IS NOT CONCURRENTLY USING AN ALPHA-GAL A PHARMACOLOGICAL CHAPERONE (I.E. GALAFOLD (MIGALASTAT)). THE PATIENT IS SYMPTOMATIC OR HAS EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS. |
| <b>Age Restrictions</b>             | 8 YEARS OF AGE OR OLDER   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| <b>Other Criteria</b>               | FABRY DISEASE RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS DEMONSTRATED IMPROVEMENT OR STABILIZATION.  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ALECTINIB

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## Products Affected

- ALECENSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ALEMTUZUMAB - LEMTRADA

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## Products Affected

- LEMTRADA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | RENEWAL: AT LEAST 12 MONTHS HAVE ELAPSED SINCE THE PATIENT RECEIVED THE MOST RECENT COURSE OF LEMTRADA. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ALIROCUMAB

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## Products Affected

- PRALUENT PEN

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

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL WHILE ON MAXIMAL DRUG TREATMENT. MEETS ONE OF THE FOLLOWING: (1) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, (2) 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, (3) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), (4) STATIN INTOLERANCE, OR (5) PATIENT HAS TRIED ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY). RENEWAL: PATIENT MEETS ONE OF THE FOLLOWING: 1) CONTINUED CONCURRENT THERAPY WITH A MAXIMALLY TOLERATED DOSE OF A STATIN, 2) STATIN INTOLERANCE, OR 3) A CONTRAINDICATION TO STATIN THERAPY.</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# ALPELISIB

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## 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               |                               |



# AMANTADINE

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## Products Affected

- GOCOVRI ORAL  
CAPSULE, EXTENDED RELEASE  
24HR 137 MG, 68.5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ANAKINRA

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## Products Affected

- KINERET

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| Other Criteria               | INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, RINVOQ, ENBREL, XELJANZ. RENEWAL: RA: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# APALUTAMIDE

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## Products Affected

- ERLEADA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | INITIAL: NON METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): THE PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): PATIENT MEETS ONE OF THE FOLLOWING: (1) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST OR ANTAGONIST OR (2) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY. RENEWAL: A DIAGNOSIS OF NMCRPC OR MCSPC. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# APOMORPHINE - SL

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# APOMORPHINE HCL

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## Products Affected

- APOKYN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION OF PATIENT IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF APOKYN. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PHYSICIAN ATTESTATION OF OPTIMIZATION OF DRUG THERAPY FOR PARKINSON'S DISEASE.                                   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# APREMILAST

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## Products Affected

- OTEZLA
- OTEZLA STARTER

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# ASFOTASE

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## Products Affected

- STRENSIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION, SERUM ALKALINE PHOSPHATASE (ALP) LEVEL, SERUM PYRIDOXAL-5'-PHOSPHATE (PLP) LEVELS, URINE PHOSPHOETHANOLAMINE (PEA) LEVEL, RADIOGRAPHIC EVIDENCE OF HYPOPHOSPHATASIA (HPP) |
| <b>Age Restrictions</b>             | PERINATAL/INFANTILE-ONSET HYPOPHOSPHATASIA (HPP): 6 MONTHS OF AGE OR YOUNGER AT HYPOPHOSPHATASIA (HPP) ONSET. JUVENILE-ONSET HYPOPHOSPHATASIA (HPP): 18 YEARS OF AGE OR YOUNGER AT HYPOPHOSPHATASIA (HPP) ONSET.                           |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ENDOCRINOLOGIST, A GENETICIST, OR A METABOLIC SPECIALIST.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: FOR PATIENTS WITH PERINATAL/INFANTILE-ONSET HYPOPHOSPHATASIA (HPP), ALL OF THE FOLLOWING CRITERIA MUST BE MET: POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR MEETS AT LEAST TWO OF THE FOLLOWING CRITERIA: 1.) SERUM ALKALINE PHOSPHATASE (ALP) LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE 2.) SERUM PYRIDOXAL-5'-PHOSPHATE (PLP) LEVELS ELEVATED AND PATIENT HAS NOT RECEIVED VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK 3.) URINE PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE 4.) RADIOGRAPHIC EVIDENCE OF HYPOPHOSPHATASIA (HPP) (E.G., FLARED AND FRAYED METAPHYSES, OSTEOPENIA, WIDENED GROWTH PLATES, AREAS OF RADIOLUCENCY OR SCLEROSIS) 5.) PRESENCE OF TWO OR MORE OF THE FOLLOWING: RACHITIC CHEST DEFORMITY, CRANIOSYNOSTOSIS (PREMATURE CLOSURE OF SKULL BONES), DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, HISTORY OF VITAMIN B6 DEPENDENT SEIZURES, NEPHROCALCINOSIS, OR HISTORY OF ELEVATED SERUM CALCIUM. HISTORY OR PRESENCE OF NON-TRAUMATIC POSTNATAL FRACTURE AND DELAYED FRACTURE HEALING. FOR PATIENTS WITH JUVENILE-ONSET HYPOPHOSPHATASIA (HPP), ALL OF THE FOLLOWING CRITERIA MUST BE MET: POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR MEETS AT LEAST TWO OF THE FOLLOWING CRITERIA: 1.) SERUM ALKALINE PHOSPHATASE (ALP) LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE 2.) SERUM PYRIDOXAL-5'-</p> |



| PA Criteria           | Criteria Details  |
|-----------------------|---|
|                       | <p>PHOSPHATE (PLP) LEVELS ELEVATED AND PATIENT HAS NOT RECEIVED VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK 3.)URINE PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE 4.)RADIOGRAPHIC EVIDENCE OF HYPOPHOSPHATASIA (HPP) (E.G., FLARED AND FRAYED METAPHYSES, OSTEOPENIA, OSTEOMALACIA, WIDENED GROWTH PLATES, AREAS OF RADIOLUCENCY OR SCLEROSIS) 5.)PRESENCE OF TWO OR MORE OF THE FOLLOWING:RACHITIC DEFORMITIES (RACHITIC CHEST, BOWED LEGS, KNOCK-KNEES),PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 YEARS OF AGE, DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, OR HISTORY OR PRESENCE OF NON-TRAUMATIC FRACTURES OR DELAYED FRACTURE HEALING. STRENSIQ WILL NOT BE APPROVED FOR THE FOLLOWING PATIENTS: PATIENTS CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE [E.G., BONIVA (IBANDRONATE), FOSAMAX (ALENDRONATE), ACTONEL (RISEDRONATE)], PATIENTS WITH SERUM CALCIUM OR PHOSPHATE LEVELS BELOW THE NORMAL RANGE, PATIENTS WITH A TREATABLE FORM OF RICKETS. RENEWAL: PATIENT HAS EXPERIENCED AN IMPROVEMENT IN THE SKELETAL CHARACTERISTICS OF HYPOPHOSPHATASIA (HPP) (E.G., IMPROVEMENT OF THE IRREGULARITY OF THE PROVISIONAL ZONE OF CALCIFICATION, PHYSEAL WIDENING, METAPHYSEAL FLARING, RADIOLUCENCIES, PATCHY OSTEOSCLEROSIS, RATIO OF MID-DIAPHYSEAL CORTEX TO BONE THICKNESS, GRACILE BONES, BONE FORMATION AND FRACTURES.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# ASPARAGINASE

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## Products Affected

- ONCASPAR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ATEZOLIZUMAB

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## Products Affected

- TECENTRIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# AVAPRITINIB

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## Products Affected

- AYVAKIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# AVATROMBOPAG

## Products Affected

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

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | CHRONIC LIVER DISEASE (CLD): PATIENT HAS A PLANNED PROCEDURE 10 TO 13 DAYS AFTER INITIATION OF DOPTELET. PATIENT IS NOT RECEIVING OTHER THROMBOPOIETIN RECEPTOR AGONISTS (E.G. ROMIPLOSTIM, ELTROMBOPAG, ETC.). CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: PREVIOUS TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS OR IMMUNOGLOBULINS OR INSUFFICIENT RESPONSE TO SPLENECTOMY, RENEWAL: PHYSICIAN ATTESTATION OF A CLINICAL RESPONSE. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | CLD: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, OR ENDOCRINOLOGIST. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.   |
| <b>Coverage Duration</b>            | CLD: 1 MONTH. CHRONIC ITP: INITIAL: 2 MONTHS, RENEWAL: 12 MONTHS.   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# AVELUMAB

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## Products Affected

- BAVENCIO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# AXITINIB

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# AZACITIDINE

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## Products Affected

- ONUREG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# AZTREONAM LYSINE

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## Products Affected

- CAYSTON

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             | AT LEAST 7 YEARS OLD          |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BARICITINIB

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## Products Affected

- OLUMIANT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| Other Criteria               | INITIAL FOR RA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. RENEWAL FOR RA: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# BEDAQUILINE FUMARATE

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## Products Affected

- SIRTURO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 24 WEEKS  |
| <b>Other Criteria</b>               | SIRTURO USED IN COMBINATION WITH AT LEAST 3 OTHER ANTIBIOTICS FOR THE TREATMENT OF PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# BELANTAMAB MAFODOTIN-BLMF

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## Products Affected

- BLENREP

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BELIMUMAB

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## Products Affected

- BENLYSTA INTRAVENOUS
- BENLYSTA SUBCUTANEOUS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | AUTOANTIBODY POSITIVE LUPUS TEST.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: MEMBER IS CURRENTLY TAKING CORTICOSTEROIDS, ANTIMALARIALS, NSAIDS, OR IMMUNOSUPPRESSIVE AGENTS. NO APPROVAL FOR DIAGNOSIS OF SEVERE ACTIVE LUPUS NEPHRITIS, SEVERE CENTRAL NERVOUS SYSTEM LUPUS OR CONCURRENT USE OF BIOLOGIC AGENTS OR INTRAVENOUS CYCLOPHOSPHAMIDE. RENEWAL: PHYSICIAN ATTESTATION OF IMPROVEMENT. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# BELINOSTAT

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## Products Affected

- BELEODAQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BEMPEDOIC ACID

## Products Affected

- NEXLETOL
- NEXLIZET

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL.  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST  |
| Coverage Duration            | INITIAL AND RENEWAL: 12 MONTHS   |
| Other Criteria               | INITIAL FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA: TRIAL OF OR CONTRAINDICATION TO EZETIMIBE. ALL INDICATIONS: INITIAL: MEETS ONE OF THE FOLLOWING: (1) TRIAL OF A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY), (2) TAKING A MAXIMALLY TOLERATED DOSE OF ANY STATIN GIVEN THAT THE PATIENT CANNOT TOLERATE A HIGH-INTENSITY STATIN, (3) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTION), (4) STATIN INTOLERANCE, OR (5) SKELETAL-MUSCLE EVENTS WHILE ON STATIN THERAPY. RENEWAL: MEETS ONE OF THE FOLLOWING: (1) LDL-C LOWERING AND CONTINUED THERAPY WITH A MAXIMALLY TOLERATED DOSE OF ANY STATIN, (2) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY, OR (3) COMPLETE STATIN INTOLERANCE. |
| Indications                  | All FDA-approved Indications.  |

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |



# BENDAMUSTINE

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## Products Affected

- BENDEKA
- TREANDA INTRAVENOUS RECON SOLN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BENRALIZUMAB

## Products Affected

- FASENRA
- FASENRA PEN

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | INITIAL: CONCURRENT USE OF XOLAIR, DUPIXENT, OR OTHER ANTI-IL5 BIOLOGICS   |
| <b>Required Medical Information</b> | INITIAL: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | INITIAL: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: 1) PRIOR THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY-TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION AND 2) PATIENT HAS EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION IN THE PAST 12 MONTHS (DEFINED AS AN ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT, OR SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS). RENEWAL: PATIENT HAS SHOWN A CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: 1) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, 2) DECREASED UTILIZATION OF RESCUE MEDICATIONS, 3) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR 4) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |

|                       |                         |
|-----------------------|-------------------------|
| <b>PA Criteria</b>    | <b>Criteria Details</b> |
| <b>Off Label Uses</b> |                         |

# BEVACIZUMAB

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## Products Affected

- AVASTIN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BEVACIZUMAB-AWWB

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## Products Affected

- MVASI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BEVACIZUMAB-BVZR

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## Products Affected

- ZIRABEV

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BEXAROTENE

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## Products Affected

- *bexarotene*
- TARGRETIN TOPICAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BINIMETINIB

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## Products Affected

- MEKTOVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# BLINATUMOMAB

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## Products Affected

- BLINCYTO INTRAVENOUS KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | INITIAL: RELAPSED OR REFRACTORY B-CELL: 3 MOS.<br>MRD-POSITIVE B-CELL: 2 MOS. RENEWAL: 12 MOS. |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: RELAPSED OR REFRACTORY B-CELL PRECURSOR ALL: APPROVAL IS FOR 2 CYCLES, MAY APPROVE FOR 1 ADDITIONAL CYCLE DUE TO TREATMENT INTERRUPTION FOR DOSE MODIFICATION. RENEWAL: FOR DIAGNOSIS OF RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL), RENEWAL IS APPROVED FOR PATIENTS WHO HAVE ACHIEVED COMPLETE REMISSION (CR) OR CR WITH PARTIAL HEMATOLOGICAL RECOVERY OF PERIPHERAL BLOOD COUNTS AFTER 2 CYCLES OF TREATMENT. RENEWAL IS NOT APPROVED FOR PATIENTS WHO RECEIVED AN ALLOGENEIC HEMATOPOIETIC STEM-CELL TRANSPLANT. FOR DIAGNOSIS OF MINIMAL RESIDUAL DISEASE (MRD)-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL), RENEWAL IS APPROVED FOR PATIENTS WHO HAVE ACHIEVED UNDETECTABLE MINIMAL RESIDUAL DISEASE (MRD) WITHIN ONE CYCLE OF BLINCYTO TREATMENT AND IS RELAPSE-FREE (I.E., HEMATOLOGICAL OR EXTRAMEDULLARY RELAPSE, OR SECONDARY LEUKEMIA). THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# BORTEZOMIB

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## Products Affected

- BORTEZOMIB
- VELCADE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BOSUTINIB

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | CHRONIC, ACCELERATED, OR BLAST PHASE PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOGENOUS LEUKEMIA: BCR-ABL MUTATIONAL ANALYSIS CONFIRMING THAT T315I, V299L, G250E, OR F317L MUTATIONS ARE NOT PRESENT. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# BRENTUXIMAB

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## Products Affected

- ADCETRIS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BRIGATINIB

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# BRODALUMAB

## Products Affected

- SILIQ

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS: PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5% OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PLAQUE PSORIASIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. PATIENT HAS BEEN COUNSELED ON AND EXPRESSES UNDERSTANDING OF THE RISK OF SUICIDAL IDEATION AND BEHAVIOR. RENEWAL: PSO: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION AND HAS NOT DEVELOPED OR REPORTED WORSENING DEPRESSIVE SYMPTOMS OR SUICIDAL IDEATION AND BEHAVIORS WHILE ON TREATMENT WITH SILIQ. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# C1 ESTERASE INHIBITOR-CINRYZE, BERINERT

## Products Affected

- CINRYZE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | CINRYZE RENEWAL: PHYSICIAN ATTESTATION OF IMPROVEMENT (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY) IN HAE ATTACKS WITH ROUTINE PROPHYLAXIS.                  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: DIAGNOSIS OF HEREDITARY ANGIOEDEMA CONFIRMED BY COMPLEMENT TESTING. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# C1 ESTERASE INHIBITOR-HAEGARDA, RUCONEST

## Products Affected

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

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | HAEGARDA RENEWAL: PHYSICIAN ATTESTATION OF IMPROVEMENT (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY) IN HAE ATTACKS WITH ROUTINE PROPHYLAXIS. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: DIAGNOSIS OF HEREDITARY ANGIOEDEMA CONFIRMED BY COMPLEMENT TESTING.  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# CABOZANTINIB

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## Products Affected

- COMETRIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CABOZANTINIB S-MALATE - CABOMETYX

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## Products Affected

- CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CANAKINUMAB

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## Products Affected

- ILARIS (PF) SUBCUTANEOUS SOLUTION

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR AN IMMUNOLOGIST. |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# CANNABIDIOL

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## Products Affected

- EPIDIOLEX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.  |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | LENNOX-GASTAUT SYNDROME (LGS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CLOBAZAM, TOPIRAMATE, LAMOTRIGINE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# CAPLACIZUMAB YHDP

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## Products Affected

- CABLIVI INJECTION KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# CAPMATINIB

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## Products Affected

- TABRECTA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CARFILZOMIB

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## Products Affected

- KYPROLIS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# CEMIPLIMAB

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## Products Affected

- LIBTAYO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CERITINIB

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## Products Affected

- ZYKADIA ORAL TABLET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CERTOLIZUMAB PEGOL

## Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | INITIAL: PLAQUE PSORIASIS: PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5% OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: PATIENT HAS ONE OF THE FOLLOWING OBJECTIVE SIGNS OF INFLAMMATION: 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).            |
| Age Restrictions             |  |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS/ANKYLOSING SPONDYLITIS/NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. CROHNS DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST. PLAQUE PSORIASIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA) PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. CROHNS DISEASE (CD): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA. PATIENTS WHO ARE PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT ARE EXCLUDED FROM STEP CRITERIA FOR ALL INDICATIONS. RENEWAL FOR RA, PSA, AS, PSO OR NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# 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 | RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS DEMONSTRATED CLINICAL BENEFIT COMPARED TO PRE TREATMENT BASELINE AND THE PATIENT DOES NOT HAVE LYMPHOPENIA. |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 48 WEEKS  |
| Other Criteria               |   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# CLOBAZAM

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## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | TRIAL OF OR CONTRAINDICATION TO LAMOTRIGINE OR TOPIRAMATE. REQUESTS FOR ORAL SUSPENSION APPROVABLE IF PATIENT IS UNABLE TO SWALLOW OR IS UNDER THE AGE OF 5 YEARS. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CLOBAZAM-SYMPAZAN

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## Products Affected

- SYMPAZAN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | PHYSICIAN ATTESTATION THAT THE PATIENT IS UNABLE TO TAKE TABLETS OR SUSPENSION. TRIAL OF OR CONTRAINDICATION TO A FORMULARY CLOBAZAM AGENT. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# COBIMETINIB FUMARATE

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## Products Affected

- COTELLIC

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# COLCHICINE

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## Products Affected

- *colchicine oral tablet*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | PROPHYLAXIS OF GOUT FLARES: 16 YEARS AND OLDER  |
| Prescriber Restrictions      |   |
| Coverage Duration            | 12 MONTHS   |
| Other Criteria               | TRIAL OF OR CONTRAINDICATION TO COLCHICINE CAPSULES (MITIGARE) WHERE INDICATIONS ALIGN. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# COPANLISIB DI-HCL

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## Products Affected

- ALIQOPA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# CRIZANLIZUMAB-TMCA

## Products Affected

- ADAKVEO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | SICKLE CELL DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST   |
| <b>Coverage Duration</b>            | INITIAL: 12 MONTHS. RENEWAL: LIFETIME   |
| <b>Other Criteria</b>               | SICKLE CELL DISEASE: INITIAL CRITERIA FOR ADULTS (18 YEARS OR OLDER): PATIENT HAS ONE OF THE FOLLOWING: (1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, (2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR (3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME (ACS). INITIAL REQUESTS FOR PATIENTS BETWEEN THE AGES OF 16 TO 17 YEARS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. RENEWAL FOR ALL PATIENTS: MAINTAINED OR EXPERIENCED REDUCTION IN ACUTE COMPLICATIONS OF SICKLE CELL DISEASE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# CRIZOTINIB

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## Products Affected

- XALKORI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DABRAFENIB MESYLATE

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## Products Affected

- TAFINLAR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DACOMITINIB

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## Products Affected

- VIZIMPRO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DALFAMPRIDINE

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## Products Affected

- *dalfampridine*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | WALKING DISABILITY SUCH AS MILD TO MODERATE BILATERAL LOWER EXTREMITY WEAKNESS OR UNILATERAL WEAKNESS PLUS LOWER EXTREMITY OR TRUNCAL ATAXIA. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | NEUROLOGIST   |
| <b>Coverage Duration</b>            | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | RENEWAL: PHYSICIAN ATTESTATION OF IMPROVEMENT IN WALKING ABILITY.   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# DARATUMUMAB

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## Products Affected

- DARZALEX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# DARATUMUMAB-HYALURONIDASE-FIHJ

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## Products Affected

- DARZALEX FASPRO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DAROLUTAMIDE

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## Products Affected

- NUBEQA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: NON METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): THE PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS) AND MEETS ONE OF THE FOLLOWING: (1) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST OR ANTAGONIST OR (2) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY. RENEWAL: A DIAGNOSIS OF NMCRPC. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# DASATINIB

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | PREVIOUSLY-TREATED CHRONIC MYELOID LEUKEMIA (CML) REQUIRES BCR-ABL MUTATIONAL ANALYSIS NEGATIVE FOR THE FOLLOWING MUTATIONS: T315I, V299L, T315A, F317L/V/I/C. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# DECITABINE/CEDAZURIDINE

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## Products Affected

- INQOVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# DEFERASIROX

## Products Affected

- *deferasirox*

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

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# DEFERIPRONE

## Products Affected

- FERRIPROX

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| <b>Other Criteria</b>               | INITIAL CRITERIA: REQUIRES TRIAL OF OR CONTRAINDICATION TO A FORMULARY PREFERRED VERSION OF EXJADE, JADENU, OR DESFERAL AND ONE OF THE FOLLOWING CRITERIA 1) PATIENT IS EXPERIENCING INTOLERABLE TOXICITIES OR CLINICALLY SIGNIFICANT ADVERSE EFFECTS OR HAS A CONTRAINDICATION TO THESE THERAPIES OR 2) INADEQUATE CHELATION DEFINED BY ONE OF THE FOLLOWING: A) SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 2500 MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS) OR B) EVIDENCE OF CARDIAC IRON ACCUMULATION (I.E., CARDIAC T2 STAR MRI LESS THAN 10 MILLISECONDS, IRON INDUCED CARDIOMYOPATHY, FALL IN LEFT VENTRICULAR EJECTION FRACTION, ARRHYTHMIA INDICATING INADEQUATE CHELATION). RENEWAL: SERUM FERRITIN LEVELS MUST BE CONSISTENTLY ABOVE 500MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). |
| <b>Indications</b>                  | All FDA-approved Indications.  |

|                       |                         |
|-----------------------|-------------------------|
| <b>PA Criteria</b>    | <b>Criteria Details</b> |
| <b>Off Label Uses</b> |                         |



# DEFEROXAMINE

## Products Affected

- *deferoxamine*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | CHRONIC IRON OVERLOAD: AT LEAST 3 YEARS OF AGE OR OLDER  |
| <b>Prescriber Restrictions</b>      | CHRONIC IRON OVERLOAD: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| <b>Other Criteria</b>               | INITIAL: CHRONIC IRON OVERLOAD: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 1000MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). RENEWAL: CHRONIC IRON OVERLOAD: SERUM FERRITIN LEVELS MUST BE CONSISTENTLY ABOVE 500MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# DEFLAZACORT

## Products Affected

- EMFLAZA ORAL SUSPENSION
- EMFLAZA ORAL TABLET 18 MG, 30 MG, 36 MG, 6 MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | PHYSICIAN ATTESTATION OF GENETIC TESTING CONFIRMING DMD DIAGNOSIS.  |
| Age Restrictions             |   |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST.  |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| Other Criteria               | INITIAL CRITERIA: REQUIRE TRIAL OF PREDNISONE OR PREDNISOLONE AND PATIENT MEETS ONE OF THE FOLLOWING: 1) REQUEST DUE TO ADVERSE EFFECTS OF PREDNISONE OR PREDNISOLONE OR 2) REQUEST DUE TO LACK OF EFFICACY OF PREDNISONE OR PREDNISOLONE AND ALL OF THE FOLLOWING CRITERIA ARE MET: A) PATIENT IS NOT IN STAGE 1 (PRE-SYMPTOMATIC PHASE) B) STEROID MYOPATHY HAS BEEN RULED OUT C) PHYSICIAN ATTESTATION OF DETERIORATION IN AMBULATION, FUNCTIONAL STATUS, OR PULMONARY FUNCTION CONSISTENT WITH ADVANCING DISEASE. RENEWAL CRITERIA: PATIENT HAS MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E. PULMONARY OR CARDIAC FUNCTION). |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# DELAFLOXACIN

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## Products Affected

- BAXDELA ORAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Exclusion Criteria</b>           |                         |
| <b>Required Medical Information</b> |                         |
| <b>Age Restrictions</b>             |                         |
| <b>Prescriber Restrictions</b>      |                         |
| <b>Coverage Duration</b>            | ONE MONTH               |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI): ONE OF THE FOLLOWING: 1) PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, OR 2) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO DELAFLOXACIN AND RESISTANCE TO ONE STANDARD OF CARE AGENT FOR ABSSSI, OR 3) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED FORMULARY AGENTS FOR ABSSSI: A PENICILLIN, A FLUOROQUINOLONE, A CEPHALOSPORIN, OR A GRAM POSITIVE TARGETING ANTIBIOTIC.</p> <p>COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): ONE OF THE FOLLOWING: 1) PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST, OR 2) ANTIMICROBIAL SUSCEPTIBILITY TESTING SHOWS SUSCEPTIBILITY TO DELAFLOXACIN AND RESISTANCE TO AT LEAST TWO STANDARD OF CARE AGENTS FOR CABP, OR 3) IF SENSITIVITY RESULTS ARE UNAVAILABLE: TRIAL OF OR CONTRAINDICATION TO AT LEAST TWO STANDARD OF CARE AGENTS FOR CABP.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# DENOSUMAB-XGEVA

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## Products Affected

- XGEVA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DEUTETRABENAZINE

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## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | TARDIVE DYSKINESIA: PATIENT HAS A PRIOR HISTORY OF USING ANTIPSYCHOTIC MEDICATIONS OR METOCLOPRAMIDE PER PHYSICIAN ATTESTATION  |
| Age Restrictions             |   |
| Prescriber Restrictions      | HUNTINGTON DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST. TARDIVE DYSKINESIA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST |
| Coverage Duration            | 12 MONTHS   |
| Other Criteria               |   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# DEXTROMETHORPHAN QUINIDINE

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## Products Affected

- NUEDEXTA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                        |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS                                      |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All Medically-accepted Indications.            |
| <b>Off Label Uses</b>               |  |

# DICHLORPHENAMIDE

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## Products Affected

- KEVEYIS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | HEPATIC INSUFFICIENCY, PULMONARY OBSTRUCTION, OR A HEALTH CONDITION THAT WARRANTS CONCURRENT USE OF HIGH-DOSE ASPIRIN |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | 18 YEARS AND OLDER  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: 2 MONTHS RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | RENEWAL REQUIRES PHYSICIAN ATTESTATION OF IMPROVEMENT.  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# DICLOFENAC EPOLAMINE

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## Products Affected

- *diclofenac epolamine*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                        |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS                                      |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All Medically-accepted Indications.            |
| <b>Off Label Uses</b>               |  |

# DICLOFENAC TOPICAL

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## Products Affected

- *diclofenac sodium topical gel 3 %*
- PENNSAID TOPICAL SOLUTION IN METERED-DOSE PUMP

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | PENNSAID 2% TOPICAL SOLUTION: TRIAL OF OR CONTRAINDICATION TO FORMULARY DICLOFENAC SODIUM 1% TOPICAL GEL AND DICLOFENAC SODIUM 1.5% TOPICAL DROPS. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DIMETHYL FUMARATE

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## Products Affected

- TECFIDERA ORAL  
CAPSULE, DELAYED  
RELEASE(DR/EC) 120 MG, 120 MG  
(14)- 240 MG (46), 240 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DINUTUXIMAB

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## Products Affected

- UNITUXIN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DIROXIMEL FUMARATE

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## Products Affected

- VUMERITY

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DRONABINOL

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## Products Affected

- *dronabinol*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 6 MONTHS  |
| Other Criteria               | B VS D COVERAGE CONSIDERATION. PART D COVERAGE CONSIDERATION FOR A DIAGNOSIS OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY REQUIRES A TRIAL OF OR CONTRAINDICATION TO CONVENTIONAL ANTIEMETIC THERAPIES. NO ADDITIONAL REQUIREMENTS FOR A DIAGNOSIS OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# DROXIDOPA

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## Products Affected

- NORTHERA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | BLOOD PRESSURE READINGS WHILE THE PATIENT IS SITTING AND ALSO WITHIN 3 MINUTES OF STANDING FROM A SUPINE (LYING FACE UP) POSITION AT BASELINE AND RENEWAL.  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST OR CARDIOLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 3 MONTHS RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: DIAGNOSIS OF ORTHOSTATIC HYPOTENSION AS DOCUMENTED BY 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. RENEWAL: PATIENT HAD AN INCREASE IN SYSTOLIC BLOOD PRESSURE FROM BASELINE OF AT LEAST 10 MMHG UPON STANDING FROM A SUPINE (LYING FACE UP) POSITION. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# DUPILUMAB

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## Products Affected

- DUPIXENT PEN
- DUPIXENT SYRINGE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | INITIAL: ASTHMA: CONCURRENT USE OF XOLAIR OR ANTI-IL5 BIOLOGICS.   |
| <b>Required Medical Information</b> | INITIAL APPROVAL FOR EOSINOPHILIC ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | INITIAL: ATOPIC DERMATITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. CHRONIC RHINOSINUSITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: ATOPIC DERMATITIS, CRSWNP: 6 MOS, ASTHMA: 12 MOS. RENEWAL: 12 MOS (ALL INDICATIONS).  |



| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL APPROVAL FOR ATOPIC DERMATITIS REQUIRES: 1) PREVIOUS TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING: TOPICAL CORTICOSTEROIDS, TOPICAL CALCINEURIN INHIBITORS OR TOPICAL PDE4 INHIBITOR. 2) ATOPIC DERMATITIS INVOLVING AT LEAST 10% OF BODY SURFACE AREA (BSA) OR ATOPIC DERMATITIS AFFECTING THE FACE, HEAD, NECK, HANDS, FEET, GROIN, OR INTERTRIGINOUS AREAS. 3) INTRACTABLE PRURITUS OR CRACKING/OOZING/BLEEDING OF AFFECTED SKIN.</p> <p>INITIAL APPROVAL FOR ASTHMA: 1) PRIOR THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY-TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION. 2) PATIENT HAS EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION IN THE PAST 12 MONTHS (DEFINED AS AN ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT, OR SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS).</p> <p>INITIAL APPROVAL FOR CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSWNP) REQUIRES: 1) EVIDENCE OF NASAL POLYPS BY DIRECT EXAMINATION, ENDOSCOPY OR SINUS CT SCAN, 2) PATIENT HAS INADEQUATELY CONTROLLED DISEASE AS DETERMINED BY THE USE OF SYSTEMIC STEROIDS IN THE PAST 2 YEARS OR ENDOSCOPIC SINUS SURGERY.</p> <p>RENEWAL FOR ATOPIC DERMATITIS AND CHRONIC RHINOSINUSITIS: PATIENT IMPROVEMENT ON THERAPY.</p> <p>RENEWAL FOR ASTHMA: PATIENT HAS SHOWN A CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: 1) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, 2) DECREASED UTILIZATION OF RESCUE MEDICATIONS, 3) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT</p> |
|                       | BASELINE, OR 4) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS.  |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# DURVALUMAB

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## Products Affected

- IMFINZI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# DUVELISIB

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## Products Affected

- COPIKTRA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# EDARAVONE

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## Products Affected

- RADICAVA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ELAGOLIX SODIUM

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## Products Affected

- ORLISSA ORAL TABLET 150 MG, 200 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | 18 YEARS OF AGE AND OLDER  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH AN OBSTETRICIAN/GYNECOLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: PREVIOUS TRIAL OF OR CONTRAINDICATION TO NSAID AND PROGESTIN-CONTAINING CONTRACEPTIVE PREPARATION.<br>RENEWAL: MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: IMPROVEMENT IN PAIN ASSOCIATED WITH ENDOMETRIOSIS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ELAPEGADEMASE-LVLR

## Products Affected

- REVCOVI

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | INITIAL: ADENOSINE DEAMINASE SEVERE COMBINED IMMUNE DEFICIENCY (ADA-SCID): PRESCRIBED BY OR IN CONSULTATION WITH IMMUNOLOGIST, HEMATOLOGIST/ONCOLOGIST, OR PHYSICIAN SPECIALIZING IN INHERITED METABOLIC DISORDERS  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| <b>Other Criteria</b>               | INITIAL: ADA-SCID: ADA-SCID AS MANIFESTED BY ONE OF THE FOLLOWING: 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). PATIENT ALSO MEETS ONE OF THE FOLLOWING: 1) HAS FAILED OR IS NOT A CANDIDATE FOR HEMATOPOIETIC CELL TRANSPLANTATION (HCT) OR 2) REVCOVI WILL BE USED AS BRIDGING THERAPY PRIOR TO PLANNED HCT OR GENE THERAPY. RENEWAL: ADA-SCID: IMPROVEMENT OR MAINTENANCE OF IMMUNE FUNCTION FROM BASELINE AND THE PATIENT HAS NOT RECEIVED SUCCESSFUL HCT OR GENE THERAPY. |
| <b>Indications</b>                  | All FDA-approved Indications.   |

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# ELBASVIR/GRAZOPRE VIR

## Products Affected

- ZEPATIER

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | MODERATE OR SEVERE LIVER IMPAIRMENT (CHILD PUGH B OR C)  |
| <b>Required Medical Information</b> | HCV RNA LEVEL WITHIN PAST 6 MONTHS. FOR GENOTYPE 1A -TESTING FOR NS5A RESISTANCE-ASSOCIATED POLYMORPHISMS.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.   |
| <b>Coverage Duration</b>            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.  |
| <b>Other Criteria</b>               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE. NO CONCURRENT USE WITH THE FOLLOWING AGENTS: PHENYTOIN, CARBAMAZEPINE, RIFAMPIN, EFAVIRENZ, ATAZANAVIR, DARUNAVIR, LOPINAVIR, SAQUINAVIR, TIPRANAVIR, CYCLOSPORINE, NAFCILLIN, KETOCONAZOLE, MODAFINIL, BOSENTAN, ETRAVIRINE, ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR, ATORVASTATIN AT DOSES GREATER THAN 20MG PER DAY OR ROSUVASTATIN AT DOSES GREATER THAN 10MG PER DAY. |
| <b>Indications</b>                  | All FDA-approved Indications.  |



| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# ELEXACAFITOR-TEZACAFITOR-IVACAFITOR

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## Products Affected

- TRIKAFTA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: LIFETIME.  |
| <b>Other Criteria</b>               | RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ELIGLUSTAT TARTRATE

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## Products Affected

- CERDELGA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ELOSULFASE ALFA

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## Products Affected

- VIMIZIM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ELOTUZUMAB

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## Products Affected

- EMLICITI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ELTROMBOPAG

## Products Affected

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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST   |
| Coverage Duration            | ITP: INITIAL: 2 MO. RENEW: 12 MO. HCV: 12 MO. SEVERE APLASTIC ANEMIA: 12 MO.   |
| Other Criteria               | CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA PURPURA (ITP): INITIAL: TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. ALL INDICATIONS: APPROVAL FOR PROMACTA ORAL SUSPENSION PACKETS REQUIRES A TRIAL OF PROMACTA TABLETS OR PHYSICIAN ATTESTATION THAT THE PATIENT IS UNABLE TO TAKE TABLET FORMULATION. ITP: RENEWAL: PHYSICIAN ATTESTATION OF A CLINICAL RESPONSE. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ENASIDENIB

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## Products Affected

- IDHIFA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ENCORAFENIB

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## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# ENDOTHELIN RECEPTOR ANTAGONISTS

## Products Affected

- *ambrisentan* SUSPENSION
- OPSUMIT
- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. AMBRISENTAN: PATIENT DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS (IPF). FORMULARY VERSION OF BOSENTAN: PATIENT DOES NOT HAVE ELEVATED LIVER ENZYMES (ALT, AST) MORE THAN 3 TIMES UPPER LIMIT OF NORMAL (ULN) OR INCREASES IN BILIRUBIN BY 2 OR MORE TIMES ULN. PATIENT IS NOT CONCURRENTLY TAKING CYCLOSPORINE A OR GLYBURIDE. RENEWAL: PATIENT SHOW IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# ENFORTUMAB

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## Products Affected

- PADCEV

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ENTRECTINIB

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## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ENZALUTAMIDE

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## Products Affected

- XTANDI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | INITIAL: CASTRATION RESISTANT PROSTATE CANCER (CRPC) THAT IS NOT METASTATIC: THE PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): PATIENT MEETS ONE OF THE FOLLOWING: (1) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST OR ANTAGONIST OR (2) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY. RENEWAL: A DIAGNOSIS OF CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR MCSPC. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EPOPROSTENOL IV

## Products Affected

- *epoprostenol (glycine)*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS III-IV SYMPTOMS.  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. RENEWAL: PATIENT HAS SHOWN IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# EPTINEZUMAB-JJMR

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## Products Affected

- VYEPTI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE FOR PREVENTIVE MIGRAINE TREATMENT. RENEWAL: THE PATIENT HAS EXPERIENCED A REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH, OR A REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH VYEPTI THERAPY. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ERDAFITINIB

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## Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# ERENUMAB-AOOE

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## Products Affected

- AIMOVIG AUTOINJECTOR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL FOR MIGRAINE: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE FOR PREVENTIVE MIGRAINE TREATMENT. RENEWAL FOR MIGRAINE: THE PATIENT HAS EXPERIENCED A REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH OR A REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH AIMOVIG THERAPY. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ERLOTINIB

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## Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ERYTHROPOIESIS STIMULATING AGENTS - RETACRIT

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE THERAPY, OR CANCER CHEMOTHERAPY: A HEMOGLOBIN LEVEL OF LESS THAN 10G/DL. ELECTIVE NON-CARDIAC OR NON-VASCULAR SURGERY: A HEMOGLOBIN LEVEL LESS THAN 13G/DL. RENEWAL: CKD DIAGNOSIS REQUIRES ONE OF THE FOLLOWING: 1) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL OR 2) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND DOSE REDUCTION/INTERRUPTION IS REQUIRED TO REDUCE THE NEED FOR BLOOD TRANSFUSIONS. ANEMIA DUE TO ZIDOVUDINE THERAPY: A HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. ANEMIA DUE TO EFFECT OF CONCOMITANTLY ADMINISTERED CANCER CHEMOTHERAPY: A HEMOGLOBIN LEVEL OF LESS THAN 10 G/DL OR THAT THE HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE:12 MONTHS. SURGERY:1 MONTH.  |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | RENEWAL: CKD: PATIENT IS NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# ESKETAMINE

## Products Affected

- SPRAVATO NASAL SPRAY, NON-AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS DEMONSTRATED CLINICAL BENEFIT (IMPROVEMENT IN DEPRESSION) COMPARED TO BASELINE.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST.   |
| <b>Coverage Duration</b>            | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | MEETS ALL OF THE FOLLOWING: 1) PATIENT HAS NON-PSYCHOTIC, UNIPOLAR DEPRESSION, 2) PATIENT DOES NOT HAVE ACTIVE SUBSTANCE ABUSE, AND 3) PHYSICIAN ATTESTATION OF ADEQUATE TRIAL (AT LEAST 4 WEEKS) OF AT LEAST TWO ANTIDEPRESSANT AGENTS FROM DIFFERENT CLASSES THAT ARE INDICATED FOR DEPRESSION. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ETANERCEPT

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS: MODERATE TO SEVERE PLAQUE PSORIASIS INVOLVING AT LEAST 5% BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE OR GENITAL AREA.  |
| <b>Age Restrictions</b>             | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, PSORIATIC ARTHRITIS: 18 YEARS OR OLDER  |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PLAQUE PSORIASIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO 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.</p> <p>POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE DMARD. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO AN NSAID. PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY. RENEWAL: RA, PJIA, PSA, AS, PSO: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# ETEPLIRSEN

## Products Affected

- EXONDYS-51

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | PHYSICIAN ATTESTATION OF GENETIC TESTING CONFIRMING THAT MUTATION IN DUCHENNE MUSCULAR DYSTROPHY (DMD) GENE IS AMENABLE TO EXON 51 SKIPPING.  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 24 WEEKS. RENEWAL: 12 MONTHS.  |
| <b>Other Criteria</b>               | INITIAL CRITERIA: PATIENT IS AMBULATORY AND IS CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS. RENEWAL CRITERIA: PATIENT HAS MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION (I.E. PULMONARY OR CARDIAC FUNCTION) DURING THE PAST 24 WEEKS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# EVEROLIMUS

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## Products Affected

- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG, 2.5 MG, 5 MG, 7.5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | ADVANCED RENAL CELL CARCINOMA (RCC): TRIAL OF OR CONTRAINDICATION TO SUTENT OR NEXAVAR. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# EVOLOCUMAB

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## Products Affected

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

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

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH): DIAGNOSIS DETERMINED BY (1) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, (2) DUTCH LIPID NETWORK CRITERIA SCORE OF 8 OR GREATER, OR (3) A 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.</p> <p>INITIAL: ALL INDICATIONS: LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL WHILE ON MAXIMAL DRUG TREATMENT. MEETS ONE OF THE FOLLOWING: (1) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, (2) 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, (3) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), (4) STATIN INTOLERANCE, OR (5) PATIENT HAS TRIED ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY).</p> <p>RENEWAL: ALL INDICATIONS: PATIENT MEETS ONE OF THE FOLLOWING: 1) CONTINUED CONCURRENT THERAPY WITH A MAXIMALLY TOLERATED DOSE OF A STATIN, 2) STATIN INTOLERANCE, OR 3) A CONTRAINDICATION TO STATIN THERAPY.</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# FAM-TRASTUZUMAB

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## Products Affected

- ENHERTU

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# FEDRATINIB

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## 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               | INITIAL: MYELOFIBROSIS: TRIAL OF OR CONTRAINDICATION TO FORMULARY VERSION OF JAKAFI (RUXOLITINIB). RENEWAL: MYELOFIBROSIS: SYMPTOM IMPROVEMENT BY ONE OF THE FOLLOWING: 1) SPLEEN VOLUME REDUCTION OF 35% OR GREATER FROM BASELINE SPLEEN VOLUME AFTER 6 MONTHS OF THERAPY, 2) 50% OR GREATER REDUCTION IN TOTAL SYMPTOM SCORE ON THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF) V2.0, OR 3) 50% OR GREATER REDUCTION IN PALPABLE SPLEEN LENGTH. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# FENFLURAMINE

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## Products Affected

- FINTEPLA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# FENTANYL NASAL SPRAY

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## Products Affected

- LAZANDA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | CANCER RELATED PAIN: CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION. EITHER A TRIAL OR CONTRAINDICATION TO AT LEAST ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR MEMBER HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES. TRIAL OR CONTRAINDICATION TO GENERIC FENTANYL CITRATE LOZENGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# FENTANYL TRANSMUCOSAL AGENTS - FENTANYL CITRATE

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | CANCER RELATED PAIN: CURRENTLY ON A MAINTENANCE DOSE OF CONTROLLED-RELEASE OPIOID PAIN MEDICATION. EITHER A TRIAL OR CONTRAINDICATION TO AT LEAST ONE IMMEDIATE-RELEASE ORAL OPIOID PAIN AGENT OR MEMBER HAS DIFFICULTY SWALLOWING TABLETS/CAPSULES. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# FILGRASTIM

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## Products Affected

- GRANIX
- NEUPOGEN
- NIVESTYM

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST   |
| Coverage Duration            | 12 MONTHS  |
| Other Criteria               | A TRIAL OF OR CONTRAINDICATION TO ZARXIO IS REQUIRED EXCEPT WHEN USED TO INCREASE SURVIVAL IN A PATIENT ACUTELY EXPOSED TO MYELOSUPPRESSIVE DOSES OF RADIATION (HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME). |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# FINGOLIMOD

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## Products Affected

- GILENYA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# FOSTAMATINIB

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## Products Affected

- TAVALISSE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION OF A CLINICAL RESPONSE.                      |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.                                      |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# FREMANEZUMAB-VFRM

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## 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               | INITIAL FOR MIGRAINE: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE FOR PREVENTIVE MIGRAINE TREATMENT. RENEWAL FOR MIGRAINE: THE PATIENT HAS EXPERIENCED A REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH OR A REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH AJOVY THERAPY. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# GALCANEZUMAB-GNLM

## Products Affected

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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | INITIAL: MIGRAINES: 6 MOS. CLUSTER HEADACHE: 3 MOS.<br>RENEWAL (ALL INDICATIONS): 12 MONTHS.   |
| Other Criteria               | INITIAL FOR MIGRAINES: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE FOR PREVENTIVE MIGRAINE TREATMENT. CLUSTER HEADACHE: NO STEP. RENEWAL FOR MIGRAINES: THE PATIENT HAS EXPERIENCED A REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OF AT LEAST 2 DAYS PER MONTH OR A REDUCTION IN MIGRAINE SEVERITY OR MIGRAINE DURATION WITH EMGALITY THERAPY. RENEWAL FOR EPISODIC CLUSTER HEADACHE: IMPROVEMENT IN EPISODIC CLUSTER HEADACHE FREQUENCY AS COMPARED TO BASELINE. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# GEFITINIB

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## Products Affected

- IRESSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# GEMTUZUMAB OZOGAMICIN

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## Products Affected

- MYLOTARG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# GILTERITINIB

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## Products Affected

- XOSPATA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# GIVOSIRAN

## Products Affected

- GIVLAARI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: GENETIC CONFIRMATION OF MUTATION OR ELEVATED URINARY OR PLASMA PBG (PORPHOBILINOGEN) OR ALA (AMINOLEVULINIC ACID).   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | ACUTE HEPATIC PORPHYRIA (AHP): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GENETICIST, HEPATOLOGIST, HEMATOLOGIST, GASTROENTEROLOGIST, NEUROLOGIST, DERMATOLOGIST, OR A HEALTHCARE PROVIDER EXPERIENCED IN MANAGING AHP.       |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | AHP: INITIAL: HAS EXPERIENCED TWO OR MORE ACUTE HEPATIC PORPHYRIA (AHP) ATTACKS IN THE PAST 12 MONTHS. RENEWAL: 1) HAS ACHIEVED OR MAINTAINED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED A LIVER TRANSPLANT. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# GLASDEGIB

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## Products Affected

- DAURISMO ORAL TABLET 100 MG,  
25 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# GLATIRAMER ACETATE

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## Products Affected

- COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML
- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml*

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Exclusion Criteria           |                               |
| Required Medical Information |                               |
| Age Restrictions             |                               |
| Prescriber Restrictions      |                               |
| Coverage Duration            | 12 MONTHS                     |
| Other Criteria               |                               |
| Indications                  | All FDA-approved Indications. |
| Off Label Uses               |                               |

# GLECAPREVIR/PIBRENTASVIR

## Products Affected

- MAVYRET

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C)   |
| <b>Required Medical Information</b> | HCV RNA LEVEL WITHIN PAST 6 MONTHS  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH: GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.   |
| <b>Coverage Duration</b>            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.   |
| <b>Other Criteria</b>               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE. PATIENT IS NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS NOT RECOMMENDED OR CONTRAINDICATED BY THE MANUFACTURER: CARBAMAZEPINE, RIFAMPIN, ETHINYL ESTRADIOL-CONTAINING MEDICATION, ATAZANAVIR, DARUNAVIR, LOPINAVIR, RITONAVIR, EFAVIRENZ, ATORVASTATIN, LOVASTATIN, SIMVASTATIN, ROSUVASTATIN AT DOSES GREATER THAN 10MG, OR CYCLOSPORINE AT DOSES GREATER THAN 100MG PER DAY. PATIENT MUST NOT HAVE PRIOR FAILURE OF A DAA REGIMEN WITH NS5A INHIBITOR AND HCV PROTEASE INHIBITOR. |

| <b>PA Criteria</b>    | <b>Criteria Details</b>       |
|-----------------------|-------------------------------|
| <b>Indications</b>    | All FDA-approved Indications. |
| <b>Off Label Uses</b> |                               |

# GLYCEROL PHENYL BUTYRATE

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## Products Affected

- RAVICTI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | INITIAL: UREA CYCLE DISORDER (UCD): DIAGNOSIS IS CONFIRMED BY ENZYMATIC, BIOCHEMICAL OR GENETIC TESTING  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: UREA CYCLE DISORDER (UCD): TRIAL OF OR CONTRAINDICATION TO SODIUM PHENYL BUTYRATE (BUPHENYL). RENEWAL: UCD: PATIENT HAS CLINICAL BENEFIT FROM BASELINE. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# GOLIMUMAB IV

## Products Affected

- SIMPONI ARIA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| <b>Other Criteria</b>               | INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. RENEWAL: RA, PSA, AS: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# GOLIMUMAB SQ

## Products Affected

- SIMPONI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| <b>Other Criteria</b>               | INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. ULCERATIVE COLITIS (UC): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA. RENEWAL FOR RA, PSA, OR AS: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| <b>Indications</b>                  | All FDA-approved Indications.  |



| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# GUSELKUMAB

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## Products Affected

- TREMFYA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# HYDROXYUREA

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## Products Affected

- SIKLOS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# IBRUTINIB

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ICATIBANT

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## Products Affected

- *icatibant*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ALLERGIST/IMMUNOLOGIST OR HEMATOLOGIST. |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | DIAGNOSIS OF HEREDITARY ANGIOEDEMA CONFIRMED BY COMPLEMENT TESTING.                    |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# IDELALISIB

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## Products Affected

- ZYDELIG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# IMATINIB MESYLATE

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## Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA; PREVIOUS TREATMENT WITH ANOTHER TYROSINE KINASE INHIBITOR. |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 36 MONTHS. ALL OTHER DIAGNOSES: 12 MONTHS.                         |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# INFLIXIMAB

## Products Affected

- REMICADE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS: SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5% BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. RENEWAL FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, OR PLAQUE PSORIASIS: PHYSICIAN ATTESTATION THAT THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.                      |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSORIASIS PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. CROHN'S DISEASE/ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |



| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. CROHN'S DISEASE (CD): 1) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA FOR PATIENTS 18 YEARS OF AGE AND OLDER OR 2) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 6 TO 17 YEARS OLD. ULCERATIVE COLITIS (UC): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 18 YEARS OF AGE AND OLDER. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# INFLIXIMAB-ABDA

## Products Affected

- RENFLEXIS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS: SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5% BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. RENEWAL FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, OR PLAQUE PSORIASIS: PHYSICIAN ATTESTATION THAT THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.                |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSORIASIS PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHN'S DISEASE/ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PLAQUE PSORIASIS: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. CROHN'S DISEASE (CD): 1) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA FOR PATIENTS 18 YEARS OF AGE AND OLDER OR 2) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 6 TO 17 YEARS OLD. ULCERATIVE COLITIS (UC): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 18 YEARS OF AGE AND OLDER. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# INFLIXIMAB-AXXQ

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## Products Affected

- AVSOLA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSORIASIS PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. CROHN'S DISEASE/ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST. |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PLAQUE PSORIASIS (PSO): SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5% BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. CROHN'S DISEASE (CD): 1) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA FOR PATIENTS 18 YEARS OF AGE AND OLDER OR 2) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 6 TO 17 YEARS OLD. ULCERATIVE COLITIS (UC): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 18 YEARS OF AGE AND OLDER. RENEWAL FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, OR PLAQUE PSORIASIS: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# INFLIXIMAB-DYYB

## Products Affected

- INFLECTRA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | <p>INITIAL: PLAQUE PSORIASIS: SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. RENEWAL FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, OR PLAQUE PSORIASIS: PHYSICIAN ATTESTATION THAT THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p>                 |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | <p>RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSORIASIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. CROHN'S DISEASE/ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST.</p> |
| <b>Coverage Duration</b>            | <p>INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.</p>  |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: RHEUMATOID ARTHRITIS (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, SKYRIZI. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL. CROHN'S DISEASE (CD): 1) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA FOR PATIENTS 18 YEARS OF AGE AND OLDER OR 2) PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 6 TO 17 YEARS OLD. ULCERATIVE COLITIS (UC): PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA FOR PATIENTS 18 YEARS OF AGE AND OLDER. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# INOTUZUMAB OZOGAMICIN

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## Products Affected

- BESPONSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# INTERFERON ALFA-2B

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## Products Affected

- INTRON A INJECTION

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | HEPATITIS C: GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (E.G. HEPATOLOGIST).   |
| Coverage Duration            | 6 MONTHS.   |
| Other Criteria               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. LIMITED TO 1 YEAR OF THERAPY EXCEPT 18 MONTHS FOR FOLLICULAR LYMPHOMA AND 24 MONTHS FOR HEPATITIS C. HEPATITIS C GENOTYPE 1, 2, 3, 4, 5, OR 6: REQUIRES A TRIAL OF OR CONTRAINDICATION TO PEGINTERFERON ALFA-2A OR PEGINTERFERON ALFA-2B USED IN COMBINATION WITH RIBAVIRIN UNLESS CONTRAINDICATED. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# INTERFERON GAMMA-1B

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## Products Affected

- ACTIMMUNE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | CHRONIC GRANULOMATOUS DISEASE (CGD): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR IMMUNOLOGIST. SEVERE MALIGNANT OSTEOPETROSIS (SMO): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ENDOCRINOLOGIST. |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| Other Criteria               | RENEWAL: THE PATIENT HAS DEMONSTRATED CLINICAL BENEFIT COMPARED TO BASELINE AND HAS NOT RECEIVED HEMATOPOIETIC CELL TRANSPLANTATION.   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# INTERFERONS FOR MULTIPLE SCLEROSIS- EXTAVIA

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## Products Affected

- EXTAVIA SUBCUTANEOUS KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | PREVIOUS TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING: AVONEX, PLEGRIDY, REBIF, BETASERON |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# INTERFERONS FOR MULTIPLE SCLEROSIS- AVONEX, BETASERON, PLEGRIDY, REBIF

## Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR
- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT
- 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
- REBIF (WITH ALBUMIN)
- REBIF REBIDOSE SUBCUTANEOUS PEN INJECTOR 22 MCG/0.5 ML, 44 MCG/0.5 ML, 8.8MCG/0.2ML-22 MCG/0.5ML (6)
- REBIF TITRATION 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               |                               |

# IPILIMUMAB

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## Products Affected

- YERVOY

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: UNRESECT/MET MELANOMA: 4 MO, RCC/CRC/HCC: 3 MO. CUTANEOUS MELANOMA: INITIAL/RENEWAL: 6 MO  |
| <b>Other Criteria</b>               | RENEWAL FOR ADJUVANT CUTANEOUS MELANOMA: NO EVIDENCE OF DISEASE RECURRENCE (DEFINED AS THE APPEARANCE OF ONE OR MORE NEW MELANOMA LESIONS: LOCAL, REGIONAL OR DISTANT METASTASIS) |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ISATUXIMAB-IRFC

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## Products Affected

- SARCLISA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# IVACAFITOR

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## Products Affected

- KALYDECO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | HOMOZYGOUS FOR F508DEL MUTATION IN CFTR GENE.  |
| <b>Required Medical Information</b> | CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT  |
| <b>Coverage Duration</b>            | INITIAL: 12 MONTHS. RENEWAL: LIFETIME  |
| <b>Other Criteria</b>               | RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# IVOSIDENIB

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## Products Affected

- TIBSOVO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# IXAZOMIB

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## Products Affected

- NINLARO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# IXEKIZUMAB

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## Products Affected

- TALTZ AUTOINJECTOR
- TALTZ SYRINGE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS (PSO): MODERATE TO SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PLAQUE PSORIASIS (PSO): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ANKYLOSING SPONDYLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |

| <b>PA Criteria</b>    | <b>Criteria Details</b>   |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, COSENTYX, STELARA, ENBREL, SKYRIZI. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL, XELJANZ. ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, COSENTYX. RENEWAL: PSO, PSA, OR AS: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# LANADELUMAB

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## Products Affected

- TAKHZYRO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION OF IMPROVEMENT (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY) IN HAE ATTACKS WITH ROUTINE PROPHYLAXIS. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST/IMMUNOLOGIST OR HEMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL: 12 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: DIAGNOSIS OF HEREDITARY ANGIOEDEMA CONFIRMED BY COMPLEMENT TESTING.   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# LANREOTIDE ACETATE

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## Products Affected

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

# LAPATINIB DITOSYLATE

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## Products Affected

- TYKERB

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LAROTRECTINIB

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | APPROVAL FOR VITRAKVI ORAL SOLUTION REQUIRES TRIAL OF VITRAKVI CAPSULES OR PHYSICIAN ATTESTATION THAT THE PATIENT IS UNABLE TO TAKE CAPSULE FORMULATION. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# LEDIPASVIR-SOFOSBUVIR

## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | HCV RNA LEVEL WITHIN PAST 6 MONTHS.   |
| Age Restrictions             |   |
| Prescriber Restrictions      | GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.  |
| Coverage Duration            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.   |
| Other Criteria               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. PATIENT IS NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING: CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, ROSUVASTATIN, SOFOSBUVIR (AS A SINGLE AGENT), OR TIPRANAVIR/RITONAVIR. REQUESTS FOR GENERIC LEDIPASVIR/SOFOSBUVIR REQUIRE TRIAL OF OR CONTRAINDICATION TO BRAND HARVONI. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |



# LENALIDOMIDE

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## Products Affected

- REVLIMID

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LENVATINIB MESYLATE

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## Products Affected

- LENVIMA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LETERMIVIR

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 4 MONTHS                      |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LEVODOPA

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## Products Affected

- INBRIJA INHALATION CAPSULE,  
W/INHALATION DEVICE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION OF PATIENT IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF INBRIJA.                                    |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PATIENT IS NOT CURRENTLY TAKING MORE THAN 1600MG OF LEVODOPA PER DAY. PHYSICIAN ATTESTATION OF OPTIMIZATION OF DRUG THERAPY FOR PARKINSON'S DISEASE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# L-GLUTAMINE

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## Products Affected

- ENDARI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST   |
| Coverage Duration            | INITIAL: 12 MONTHS. RENEWAL: LIFETIME.   |
| Other Criteria               | INITIAL CRITERIA FOR ADULTS (18 YEARS OR OLDER): PHYSICIAN ATTESTATION OF ONE OF THE FOLLOWING: (1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR OR (2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING OR (3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME (ACS). INITIAL REQUESTS FOR PATIENTS BETWEEN THE AGES OF 5-17 WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. RENEWAL FOR ALL PATIENTS: PHYSICIAN ATTESTATION PATIENT HAS MAINTAINED OR EXPERIENCED REDUCTION IN ACUTE COMPLICATIONS OF SICKLE CELL DISEASE. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# LIDOCAINE

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## Products Affected

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

| PA Criteria                  | Criteria Details                               |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | PATCH: 12 MONTHS. OINTMENT: 3 MONTHS.          |
| Other Criteria               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| Indications                  | All Medically-accepted Indications.            |
| Off Label Uses               |  |

# LIDOCAINE PRILOCAINE

---

## Products Affected

- *lidocaine-prilocaine topical cream*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# LOMITAPIDE

---

## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                        |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | LDL CHOLESTEROL LEVEL, LDL RECEPTOR STATUS.    |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST. |
| <b>Coverage Duration</b>            | 12 MONTHS                                      |



| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>DIAGNOSIS DETERMINED BY (1) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, (2) DUTCH LIPID NETWORK CRITERIA SCORE OF 8 OR GREATER, OR (3) A 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. LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL WHILE ON MAXIMAL DRUG TREATMENT. PREVIOUS TRIAL OF EVOLOCUMAB UNLESS THE PATIENT HAS NON-FUNCTIONING LDL RECEPTORS. MEETS ONE OF THE FOLLOWING: (1) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, (2) 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, (3) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), (4) PHYSICIAN ATTESTATION OF STATIN INTOLERANCE, OR (5) PATIENT HAS TRIED ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY).</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# LORLATINIB

---

## Products Affected

- LORBRENA ORAL TABLET 100 MG,  
25 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LUMACAFITOR-IVACAFITOR

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## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: LIFETIME   |
| <b>Other Criteria</b>               | RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# LURBINECTEDIN

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## Products Affected

- ZEPZELCA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# LUSUTROMBOPAG

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## Products Affected

- MULPLETA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | PATIENT HAS A PLANNED PROCEDURE 8 TO 14 DAYS AFTER INITIATION OF MULPLETA. PATIENT IS NOT RECEIVING OTHER THROMBOPOIETIN RECEPTOR AGONISTS (E.G. AVATROMBOPAG, ROMIPLOSTIM, ELTROMBOPAG). |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, OR ENDOCRINOLOGIST.   |
| <b>Coverage Duration</b>            | 1 MONTH   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# MEMANTINE

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## Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# MEPOLIZUMAB

## Products Affected

- NUCALA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | INITIAL: ASTHMA: CONCURRENT USE OF XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS.  |
| <b>Required Medical Information</b> | INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | INITIAL: ASTHMA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN PULMONARY OR ALLERGY MEDICINE.   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: ASTHMA: PRIOR THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION. THE PATIENT HAS EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION IN THE PAST 12 MONTHS (DEFINED AS ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT, OR SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS). RENEWAL: ASTHMA: PATIENT HAS SHOWN A CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: 1) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE , 2) DECREASED UTILIZATION OF RESCUE MEDICATIONS, 3) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR 4) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |



# METHYLNALTREXONE

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## 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 | ADVANCED ILLNESS: OPIOID-INDUCED CONSTIPATION.  |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 6 MONTHS FOR PATIENTS RECEIVING PALLIATIVE CARE, 12 MONTHS FOR CHRONIC, NON-CANCER PAIN.  |
| Other Criteria               | ADVANCED ILLNESS: PATIENT IS RECEIVING PALLIATIVE CARE. CHRONIC NON-CANCER PAIN: PATIENT HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS AND HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA). |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# METHYLNALTREXONE ORAL

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## Products Affected

- RELISTOR ORAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | PATIENT HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS AND HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA). |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# MIDOSTAURIN

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## Products Affected

- RYDAPT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | ACUTE MYELOID LEUKEMIA: 6 MONTHS. ADVANCED SYSTEMIC MASTOCYTOSIS: 12 MONTHS |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# MIFEPRISTONE

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## Products Affected

- KORLYM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# MIGALASTAT HCL

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## Products Affected

- GALAFOLD

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | FABRY DISEASE INITIAL: THE PATIENT IS NOT CONCURRENTLY USING ENZYME REPLACEMENT THERAPY (I.E. FABRAZYME). THE PATIENT IS SYMPTOMATIC OR HAS EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MOS. RENEWAL: 12 MOS.  |
| <b>Other Criteria</b>               | FABRY DISEASE RENEWAL: THE PATIENT HAS DEMONSTRATED IMPROVEMENT OR STABILIZATION.   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# MIGLUSTAT

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## Products Affected

- *miglustat*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# MILTEFOSINE

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## Products Affected

- IMPAVIDO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# MOXETUMOMAB PASUDOTOX

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## Products Affected

- LUMOXITI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                                  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 6 MONTHS   |
| <b>Other Criteria</b>               | PATIENT HAS NOT PREVIOUSLY RECEIVED 6 CYCLES OF LUMOXITI |
| <b>Indications</b>                  | All FDA-approved Indications.                            |
| <b>Off Label Uses</b>               |  |



# NARCOLEPSY AGENTS

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## Products Affected

- *armodafinil*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                        |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS                                      |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All Medically-accepted Indications.            |
| <b>Off Label Uses</b>               |  |

# NATALIZUMAB

## Products Affected

- TYSABRI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | CROHN'S DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST.   |
| <b>Coverage Duration</b>            | MULTIPLE SCLEROSIS: 12 MOS. CROHN'S DISEASE: INITIAL:6 MOS. RENEWAL: 12 MOS.   |
| <b>Other Criteria</b>               | MULTIPLE SCLEROSIS (MS) INITIAL CRITERIA: PREVIOUS TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF MS. CROHN'S DISEASE INITIAL CRITERIA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA. CROHN'S DISEASE RENEWAL CRITERIA: PATIENT HAS RECEIVED AT LEAST 12 MONTHS OF THERAPY WITH TYSABRI WITH PHYSICIAN ATTESTATION THAT THE PATIENT HAS NOT REQUIRED MORE THAN 3 MONTHS OF CORTICOSTEROID USE WITHIN THE PAST 12 MONTHS TO CONTROL THEIR CROHN'S DISEASE WHILE ON TYSABRI, OR PATIENT HAS ONLY RECEIVED 6 MONTHS OF THERAPY WITH TYSABRI WITH PHYSICIAN ATTESTATION THAT THE PATIENT HAS TAPERED OFF CORTICOSTEROIDS DURING THE FIRST 24 WEEKS OF TYSABRI THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# NECITUMUMAB

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## Products Affected

- PORTRAZZA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# NERATINIB MALEATE

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## Products Affected

- NERLYNX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# NILOTINIB

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## Products Affected

- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | PREVIOUSLY TREATED CML REQUIRES BCR-ABL MUTATIONAL ANALYSIS NEGATIVE FOR THE FOLLOWING MUTATIONS: T315I, Y253H, E255K/V, AND F359V/C/I. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# NINTEDANIB

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## Products Affected

- OFEV

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# NIRAPARIB TOSYLATE

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## Products Affected

- ZEJULA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# NITISINONE

## Products Affected

- *nitisinone*
- NITYR
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | DIAGNOSIS OF HEREDITARY TYROSINEMIA TYPE 1 AS CONFIRMED BY ELEVATED URINARY OR PLASMA SUCCINYLACETONE LEVELS OR A MUTATION IN THE FUMARYLACETOACETATE HYDROLASE GENE.  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| Other Criteria               | ORFADIN SUSPENSION: TRIAL OF OR CONTRAINDICATION TO PREFERRED FORMULARY NITISINONE TABLETS OR CAPSULES. RENEWAL: THE PATIENT'S URINARY OR PLASMA SUCCINYLACETONE LEVELS HAVE DECREASED FROM BASELINE WHILE ON TREATMENT WITH NITISINONE. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |



# NIVOLUMAB

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## Products Affected

- OPDIVO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | MELANOMA: OPDIVO IS NOT APPROVED FOR COMBINATION THERAPY WITH TAFINLAR, MEKINIST (TRAMETINIB), COTELLIC (COBIMETINIB), OR ZELBORAF. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# OBETICHOLIC ACID

## Products Affected

- OCALIVA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | PATIENTS WITH COMPLETE BILIARY OBSTRUCTION.  |
| <b>Required Medical Information</b> | DIAGNOSIS OF PRIMARY BILIARY CHOLANGITIS AS CONFIRMED BY AT LEAST TWO OF THE FOLLOWING CRITERIA: AN ALKALINE PHOSPHATASE LEVEL OF AT LEAST 1.5 TIMES THE UPPER LIMIT OF NORMAL (ULN), THE PRESENCE OF ANTIMITOCHONDRIAL ANTIBODIES AT A TITER OF 1:40 OR HIGHER, HISTOLOGIC EVIDENCE OF NON-SUPPURATIVE DESTRUCTIVE CHOLANGITIS AND DESTRUCTION OF INTERLOBULAR BILE DUCTS.  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST OR HEPATOLOGIST.  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: USED IN COMBINATION WITH URSODEOXYCHOLIC ACID (E.G., URSODIOL, URSO 250, URSO FORTE) IN ADULTS WITH AN INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID AT A DOSAGE OF 13-15 MG/KG/DAY FOR AT LEAST 1 YEAR, OR AS MONOTHERAPY IN ADULTS UNABLE TO TOLERATE URSODEOXYCHOLIC ACID. RENEWAL: PATIENT'S ALKALINE PHOSPHATASE LEVELS ARE LESS THAN 1.67-TIMES THE UPPER LIMIT OF NORMAL OR HAVE DECREASED BY AT LEAST 15% FROM BASELINE WHILE ON TREATMENT WITH OBETICHOLIC ACID. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# OBINUTUZUMAB

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## Products Affected

- GAZYVA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 6 MONTHS                      |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# OCRELIZUMAB

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## Products Affected

- OCREVUS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | RELAPSING FORM OF MULTIPLE SCLEROSIS (MS): THE PATIENT HAD A PREVIOUS TRIAL OF TWO AGENTS INDICATED FOR TREATMENT OF MS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# OFATUMUMAB-SQ

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## Products Affected

- KESIMPTA PEN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# OLAPARIB

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## Products Affected

- LYNPARZA ORAL TABLET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# OMACETAXINE

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## Products Affected

- SYNRIPO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | INDUCTION: 3 MONTHS. POST INDUCTION/RENEWAL: 3 TO 12 MONTHS.  |
| Other Criteria               | CML INDUCTION THERAPY: TRIAL OF OR CONTRAINDICATION TO AT LEAST TWO OF THE FOLLOWING AGENTS: GLEEVEC, SPRYCEL, TASIGNA, BOSULIF, OR ICLUSIG. APPROVAL FOR POST-INDUCTION THERAPY DURATION WILL DEPEND ON THE PATIENT'S HEMATOLOGIC RESPONSE, DEFINED AS (1) AN ABSOLUTE NEUTROPHIL COUNT (ANC) GREATER THAN OR EQUAL TO $1.5 \times 10^9/L$ AND PLATELETS GREATER THAN OR EQUAL TO $100 \times 10^9/L$ WITHOUT BLOOD BLASTS OR (2) THE PATIENT HAS BONE MARROW BLASTS AT LESS THAN 5 PERCENT. APPROVAL IS FOR 12 MONTHS IF HEMATOLOGIC RESPONSE IS MET. IF NOT MET, APPROVAL IS FOR 3 MONTHS. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# OMALIZUMAB

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## Products Affected

- XOLAIR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | INITIAL: ASTHMA: CONCURRENT USE OF DUPIXENT OR ANTI-IL5 BIOLOGIC.   |
| <b>Required Medical Information</b> | INITIAL APPROVAL FOR ASTHMA: POSITIVE SKIN PRICK OR RAST TEST TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL GREATER THAN OR EQUAL TO 30 IU/ML.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | INITIAL: CHRONIC IDIOPATHIC URTICARIA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE, DERMATOLOGY OR IMMUNOLOGY. ASTHMA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE. |
| <b>Coverage Duration</b>            | INITIAL: ASTHMA: 12 MOS. CHRONIC IDIOPATHIC URTICARIA: 6 MOS. ALL RENEWAL: 12 MOS.  |



| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL APPROVAL FOR CHRONIC IDIOPATHIC URTICARIA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO A MAXIMALLY TOLERATED DOSE OF AN H1 ANTI-HISTAMINE AND PATIENT STILL EXPERIENCES HIVES ON MOST DAYS OF THE WEEK.</p> <p>INITIAL APPROVAL FOR ASTHMA: 1) PRIOR THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION. 2) PATIENT HAS EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION IN THE PAST 12 MONTHS (DEFINED AS AN ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT, OR SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS). 3) XOLAIR WILL BE USED AS ADD-ON MAINTENANCE TREATMENT. RENEWAL FOR ASTHMA: PATIENT HAS SHOWN A CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: 1) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE , 2) DECREASED UTILIZATION OF RESCUE MEDICATIONS, 3) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR 4) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# OMBITASVIR-PARITAPREVIR-RITONAVIR-DASABUVIR

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## Products Affected

- VIEKIRA PAK

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | DECOMPENSATED CIRRHOSIS, MODERATE OR SEVERE LIVER IMPAIRMENT (CHILD-PUGH B OR C).  |
| <b>Required Medical Information</b> | HCV RNA LEVEL WITHIN PAST 6 MONTHS.  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL. |
| <b>Coverage Duration</b>            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.  |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE. PATIENT IS NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING: ALFUZOSIN, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, GEMFIBROZIL, RIFAMPIN, ERGOTAMINE, DIHYDROERGOTAMINE, ERGONOVINE, METHYLERGONOVINE, ETHINYL ESTRADIOL CONTAINING MEDICATIONS (SUCH AS COMBINED ORAL CONTRACEPTIVES, NUVARING, ORTHO EVRA OR XULANE TRANSDERMAL PATCH SYSTEM), ST. JOHN'S WORT, LOVASTATIN, SIMVASTATIN, PIMOZIDE, EFAVIRENZ, REVATIO, TRIAZOLAM, ORAL MIDAZOLAM, DARUNAVIR/RITONAVIR, LOPINAVIR/RITONAVIR, RILPIVIRINE, SALMETEROL</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# OSIMERTINIB

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## Products Affected

- TAGRISSO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | METASTATIC NSCLC WITH EGFR T790M MUTATION: CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR. |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# OXYMETHOLONE

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## Products Affected

- ANADROL-50

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | CARCINOMA OF THE PROSTATE OR BREAST IN MALE PATIENTS, CARCINOMA OF THE BREAST IN FEMALES WITH HYPERCALCEMIA, WOMEN WHO ARE OR MAY BECOME PREGNANT, NEPHROSIS OR THE NEPHROTIC PHASE OF NEPHRITIS, HYPERSENSITIVITY TO THE DRUG AND SEVERE HEPATIC DYSFUNCTION. |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# OZANIMOD

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## Products Affected

- ZEPOSIA
- ZEPOSIA STARTER KIT
- ZEPOSIA STARTER PACK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# PALBOCICLIB

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## Products Affected

- IBRANCE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | THE PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# PALIVIZUMAB

## Products Affected

- SYNAGIS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | GESTATIONAL AGE  |
| <b>Age Restrictions</b>             | LESS THAN 24 MONTHS OF AGE.  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 1 MONTH TO 5 MONTHS. SEE OTHER CRITERIA FOR MORE INFORMATION.  |
| <b>Other Criteria</b>               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT RECOMMENDATIONS FROM THE AMERICAN ACADEMY OF PEDIATRICS FOR PALIVIZUMAB PROPHYLAXIS FOR RESPIRATORY SYNCYTIAL VIRUS INFECTIONS. INITIAL: APPROVAL WILL BE FOR AT LEAST 1 MONTH AND NO GREATER THAN 5 MONTHS DEPENDENT UPON REMAINING LENGTH OF RESPIRATORY SYNCYTIAL VIRUS (RSV) SEASON. RENEWAL: ADDITIONAL 1 MONTH OF TREATMENT FOR CARDIOPULMONARY BYPASS SURGERY DURING RSV PROPHYLAXIS SEASON. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |



# PANOBINOSTAT

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## Products Affected

- FARYDAK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | RENEWAL: PATIENT HAS TOLERATED THE FIRST 8 CYCLES OF THERAPY WITHOUT UNRESOLVED SEVERE OR MEDICALLY SIGNIFICANT TOXICITY. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# PARATHYROID HORMONE

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## Products Affected

- NATPARA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PASIREOTIDE DIASPARTATE

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## Products Affected

- SIGNIFOR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PAZOPANIB

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## Products Affected

- VOTRIENT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | PATIENT IS NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS.   |
| <b>Required Medical Information</b> | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST  |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. RENEWAL: PATIENT SHOWS IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION - IV

## Products Affected

- *sildenafil (pulm.hypertension) intravenous*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | PATIENT IS NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS.   |
| <b>Required Medical Information</b> | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST  |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. RENEWAL: PATIENT SHOWS IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# PEGFILGRASTIM

## Products Affected

- FULPHILA
- NEULASTA SUBCUTANEOUS SYRINGE
- UDENYCA
- ZIEXTENZO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST  |
| Coverage Duration            | 12 MONTHS   |
| Other Criteria               | REQUESTS FOR NEULASTA REQUIRE THAT THE PATIENT HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO FULPHILA OR UDENYCA WHERE INDICATIONS ALIGN. REQUESTS FOR NEULASTA ONPRO REQUIRE THAT THE PATIENT HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO FULPHILA OR UDENYCA WHERE INDICATIONS ALIGN OR PHYSICIAN ATTESTATION THAT THE PATIENT HAS A BARRIER TO ACCESS (E.G., TRAVEL BARRIERS, THE PATIENT IS UNABLE TO RETURN TO THE CLINIC FOR THEIR NEULASTA INJECTION). REQUESTS FOR ZIEXTENZO REQUIRE THAT THE PATIENT HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO FULPHILA OR UDENYCA WHERE INDICATIONS ALIGN. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# PEG-INTERFERON ALFA-2B-SYLATRON

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## Products Affected

- SYLATRON SUBCUTANEOUS KIT  
200 MCG, 300 MCG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                         |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS                                       |
| <b>Other Criteria</b>               | OVERALL DURATION OF THERAPY LIMITED TO 5 YEARS. |
| <b>Indications</b>                  | All FDA-approved Indications.                   |
| <b>Off Label Uses</b>               |   |



# PEGVALIASE-PQPZ

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## Products Affected

- PALYNZIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: REDUCTION IN PHENYLALANINE LEVELS BY AT LEAST 20 PERCENT FROM BASELINE OR TO A LEVEL UNDER 600 MICROMOLES PER LITER. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# PEGVISOMANT

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## Products Affected

- SOMAVERT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PEMBROLIZUMAB

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## Products Affected

- KEYTRUDA INTRAVENOUS SOLUTION

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PEMIGATINIB

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## Products Affected

- PEMAZYRE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PENICILLAMINE

## Products Affected

- *penicillamine*
- THIOLA EC

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | RHEUMATOID ARTHRITIS: HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY   |
| <b>Required Medical Information</b> | INITIAL: WILSONS DISEASE: KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE. CONFIRMATION OF ONE OF THE FOLLOWING: 1) PLASMA COPPER-PROTEIN CERULOPLASMIN IS LESS THAN 20MG/DL, 2) LIVER BIOPSY POSITIVE FOR AN ABNORMALLY HIGH CONCENTRATION OF COPPER (GREATER THAN 250MCG/G DRY WEIGHT) OR THE PRESENCE OF KAYSER-FLEISCHER RINGS, OR 3) CONFIRMATION BY GENETIC TESTING FOR ATP7B MUTATIONS. CYSTINURIA: DIAGNOSIS REQUIRES THE PRESENCE OF NEPHROLITHIASIS AND ONE OR MORE OF THE FOLLOWING: STONE ANALYSIS SHOWING PRESENCE OF CYSTEINE, IDENTIFICATION OF PATHOGNOMONIC HEXAGONAL CYSTINE CRYSTALS ON URINALYSIS, POSITIVE FAMILY HISTORY OF CYSTINURIA WITH POSITIVE CYANIDE-NITROPRUSSIDE SCREEN. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | WILSONS DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEPATOLOGIST. CYSTINURIA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEPHROLOGIST. RHEUMATOID ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL FOR ALL INDICATIONS: 12 MONTHS. RENEWAL FOR WILSONS DISEASE: 12 MONTHS   |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | INITIAL: RHEUMATOID ARTHRITIS, WILSONS DISEASE: REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRE A PREVIOUS TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN). CYSTINURIA: REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRES A PREVIOUS TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN) AND THIOLA/THIOLA EC. RENEWAL: WILSONS DISEASE: CONFIRMED DIAGNOSIS OF WILSONS DISEASE. |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# PEXIDARTINIB

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## Products Affected

- TURALIO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PIMAVANSERIN

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | 18 YEARS OR OLDER   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST, GERIATRICIAN, OR A BEHAVIORAL HEALTH SPECIALIST (SUCH AS A PSYCHIATRIST).                  |
| <b>Coverage Duration</b>            | INITIAL 12 MONTHS. RENEWAL 12 MONTHS.   |
| <b>Other Criteria</b>               | RENEWAL REQUIRES THAT THE PATIENT HAS EXPERIENCED AN IMPROVEMENT IN PSYCHOSIS SYMPTOMS FROM BASELINE AND DEMONSTRATES A CONTINUED NEED FOR TREATMENT. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# PIRFENIDONE

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## Products Affected

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 267 MG, 801 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# POLATUZUMAB VEDOTIN

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## Products Affected

- POLIVY

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# POMALIDOMIDE

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## Products Affected

- POMALYST

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PONATINIB

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## Products Affected

- ICLUSIG ORAL TABLET 15 MG, 45 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PRALSETINIB

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## Products Affected

- GAVRETO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# PRAMLINTIDE

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## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | TYPE I OR TYPE II DIABETES; REQUIRING INSULIN OR CONTINUOUS INSULIN INFUSION (INSULIN PUMP) FOR GLYCEMIC CONTROL |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | TOXOPLASMOSIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.   |
| Coverage Duration            | TOXOPLASMOSIS: INITIAL: 8 WEEKS. RENEWAL: 6 MOS.   |
| Other Criteria               | RENEWAL: CONTINUED TREATMENT OF TOXOPLASMOSIS REQUIRES 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 CURRENT ANTI-RETROVIRAL THERAPY IF HIV POSITIVE. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# RAMUCIRUMAB

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## Products Affected

- CYRAMZA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# REGORAFENIB

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## Products Affected

- STIVARGA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# RESLIZUMAB

## Products Affected

- CINQAIR

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | INITIAL: ASTHMA: CONCURRENT USE OF XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS.  |
| <b>Required Medical Information</b> | INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | INITIAL: ASTHMA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL FOR ASTHMA: 1) PRIOR THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION. 2) PATIENT HAS EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION IN THE PAST 12 MONTHS (DEFINED AS AN ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT OR SYSTEMIC CORTICOSTEROID BURST LASTING AT LEAST 3 DAYS). RENEWAL FOR ASTHMA: PATIENT HAS SHOWN A CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: 1) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, 2) DECREASED UTILIZATION OF RESCUE MEDICATIONS, 3) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR 4) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |

|                       |                         |
|-----------------------|-------------------------|
| <b>PA Criteria</b>    | <b>Criteria Details</b> |
| <b>Off Label Uses</b> |                         |

# RIBOCICLIB

## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | THE PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 12 MONTHS   |
| Other Criteria               | REQUIRES A TRIAL OF OR CONTRAINDICATION TO VERZENIO OR IBRANCE WHERE INDICATIONS ALIGN.   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# RIFAXIMIN

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## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | TRAVELERS' DIARRHEA/HEPATIC ENCEPHALOPATHY: 12 MOS. IBS-D: 12 WKS.  |
| <b>Other Criteria</b>               | FOR RIFAXIMIN 550 MG TABLETS ONLY: HEPATIC ENCEPHALOPATHY (HE); PREVIOUS TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# RIOCIQUAT

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## Products Affected

- ADEMPAS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | INITIAL FOR PAH: PATIENT IS NOT CONCURRENTLY TAKING NITRATES OR NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. INITIAL FOR CTEPH: PATIENT IS NOT CONCURRENTLY OR INTERMITTENTLY TAKING NITRATES, NITRIC OXIDE DONORS OR ANY PDE INHIBITORS.                                     |
| <b>Required Medical Information</b> | CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. DIAGNOSIS OF PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PAH AND CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS  |

| <b>PA Criteria</b>    | <b>Criteria Details</b>   |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL FOR PAH: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS AND PREVIOUS TRIAL OF OR CONTRAINDICATION TO A FORMULARY PREFERRED PHOSPHODIESTERASE-5 (PDE-5) INHIBITOR. INITIAL FOR CTEPH: PATIENT IS NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL FOR PAH AND CTEPH: PATIENT SHOWS IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# RIPRETINIB

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## Products Affected

- QINLOCK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# RISANKIZUMAB-RZAA

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## Products Affected

- SKYRIZI SUBCUTANEOUS  
SYRINGE KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# RISDIPLAM

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## Products Affected

- EVRYSDI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# RITUXIMAB

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## Products Affected

- RITUXAN

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: ONCOLOGIST.  |
| Coverage Duration            | RA: INITIAL: 6 MO. RENEWAL: 12 MONTHS. NHL, PV: 12 MONTHS. CLL: 6 MO. WG, MPA: 3 MONTHS.  |
| Other Criteria               | INITIAL: (RA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. RENEWAL: RA: THE PATIENT 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               |   |

# RITUXIMAB SQ

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## Products Affected

- RITUXAN HYCELA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THE PATIENT HAS RECEIVED OR WILL RECEIVE AT LEAST ONE FULL DOSE OF A RITUXIMAB PRODUCT BY INTRAVENOUS INFUSION PRIOR TO INITIATION OF RITUXIMAB AND HYALURONIDASE. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# RITUXIMAB-ABBS

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## Products Affected

- TRUXIMA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | NHL, CLL: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ONCOLOGIST.   |
| <b>Coverage Duration</b>            | NHL: 12 MONTHS. CLL: 6 MONTHS.   |
| <b>Other Criteria</b>               | RHEUMATOID ARTHRITIS (RA): INITIAL: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. RENEWAL: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# RITUXIMAB-PVVR

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## Products Affected

- RUXIENCE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | NHL, CLL: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ONCOLOGIST.                         |
| <b>Coverage Duration</b>            | NHL: 12 MONTHS. CLL: 6 MONTHS. WG, MPA: 3 MONTHS.  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ROMOSOZUMAB

## Products Affected

- EVENITY

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | <p>ONE OF THE FOLLOWING: (1) HIGH RISK FOR FRACTURES DEFINED AS ONE OF THE FOLLOWING: A) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S). B) 2 OR MORE RISK FACTORS FOR FRACTURE (E.G., HISTORY OF MULTIPLE RECENT LOW TRAUMA FRACTURES, BMD T-SCORE LESS THAN OR EQUAL TO -2.5, CORTICOSTEROID USE, OR USE OF GNRH ANALOGS SUCH AS NAFARELIN, ETC.). C) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR OF AT LEAST 3% FOR HIP FRACTURE. (2) UNABLE TO USE ORAL THERAPY (I.E., UPPER GASTROINTESTINAL PROBLEMS UNABLE TO TOLERATE ORAL MEDICATION, LOWER GASTROINTESTINAL PROBLEMS UNABLE TO ABSORB ORAL MEDICATIONS, TROUBLE REMEMBERING TO TAKE ORAL MEDICATIONS OR COORDINATING AN ORAL BISPHOSPHONATE WITH OTHER ORAL MEDICATIONS OR THEIR DAILY ROUTINE). (3) ADEQUATE TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO BISPHOSPHONATES.</p> |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |

|                       |                         |
|-----------------------|-------------------------|
| <b>PA Criteria</b>    | <b>Criteria Details</b> |
| <b>Off Label Uses</b> |                         |



# RUCAPARIB

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## Products Affected

- RUBRACA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# RUXOLITINIB

## Products Affected

- JAKAFI

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | MYELOFIBROSIS RENEWAL: IMPROVEMENT OR MAINTENANCE OF SYMPTOM IMPROVEMENT SUCH AS A 50% OR GREATER REDUCTION IN TOTAL SYMPTOM SCORE ON THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF) V2.0 OR 50% OR GREATER REDUCTION IN PALPABLE SPLEEN LENGTH, OR REDUCTION OF 35% OR GREATER FROM BASELINE SPLEEN VOLUME AFTER 6 MONTHS OF THERAPY. ACUTE GRAFT-VERSUS-HOST DISEASE (GVHD): NO RENEWAL CRITERIA. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | MYELOFIBROSIS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYCYTHEMIA VERA, GVHD: 12 MONTHS.   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SACITUZUMAB

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## Products Affected

- TRODELVY

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SAFINAMIDE MESYLATE

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## Products Affected

- XADAGO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SARILUMAB

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## Products Affected

- KEVZARA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: RA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. RENEWAL: RA: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# SEBELIPASE ALFA

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## Products Affected

- KANUMA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | BLOOD TEST OR DRIED BLOOD SPOT TEST INDICATING LOW OR ABSENT LYSOSOMAL ACID LIPASE DEFICIENCY (LAL) ENZYME ACTIVITY, OR A GENETIC TEST INDICATING THE PRESENCE OF ALTERED LIPA GENE(S). |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN ENDOCRINOLOGIST, HEPATOLOGIST, GASTROENTEROLOGIST, MEDICAL GENETICIST, LIPIDOLOGIST, OR A METABOLIC SPECIALIST.                          |
| <b>Coverage Duration</b>            | LAL INITIAL 6 OR 12 MONTHS, SEE OTHER CRITERIA.<br>RENEWAL: 12 MONTHS   |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>INITIAL: DIAGNOSIS OF LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY, AS CONFIRMED BY THE PRESENCE OF CLINICAL FEATURES (E.G., HEPATOMEGALY, ELEVATED SERUM TRANSAMINASES, DYSLIPIDEMIA, SPLENOMEGALY) PLUS ANY OF THE FOLLOWING: A BLOOD TEST INDICATING LOW OR ABSENT LEVELS OF LAL ENZYME ACTIVITY, A DRIED BLOOD SPOT TEST INDICATING LOW OR ABSENT LAL ENZYME ACTIVITY, OR A GENETIC TEST INDICATING THE BI-ALLELIC PRESENCE OF ALTERED LIPA GENE(S).</p> <p>RENEWAL:DIAGNOSIS OF LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE REQUIRES DOCUMENTED IMPROVEMENT IN ANY ONE OF THE FOLLOWING CLINICAL PARAMETERS ASSOCIATED WITH LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY DURING THE PAST 6 MONTHS: A RELATIVE REDUCTION FROM BASELINE IN ANY ONE OF THE FOLLOWING LIPID LEVELS (LDL-C, NON-HDL-C, OR TRIGLYCERIDES), NORMALIZATION OF ASPARTATE AMINOTRANSFERASE (AST) BASED ON AGE- AND GENDER-SPECIFIC NORMAL RANGES, A DECREASE IN LIVER FAT CONTENT COMPARED TO BASELINE ASSESSED BY ABDOMINAL IMAGING (E.G., MULTI-ECHO GRADIENT ECHO [MEGE] MRI). DIAGNOSIS OF RAPIDLY PROGRESSIVE LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE: 12 MONTHS. A DIAGNOSIS OF LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: INITIAL: 6 MONTHS</p> |
| <b>Indications</b>    | All FDA-approved Indications.  |
| <b>Off Label Uses</b> |  |

# SECUKINUMAB

## Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN (2 PENS)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | PLAQUE PSORIASIS (PSO): MODERATE TO SEVERE PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PLAQUE PSORIASIS (PSO): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST OR A DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PLAQUE PSORIASIS (PSO): PREVIOUS TRIAL OF OR CONTRAINDICATION AT LEAST ONE CONVENTIONAL THERAPY. PSORIATIC ARTHRITIS (PSA): PREVIOUS TRIAL OF OR CONTRAINDICATION TO AT LEAST ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG). ANKYLOSING SPONDYLITIS (AS): PREVIOUS TRIAL OF OR CONTRAINDICATION TO AN NSAID. RENEWAL: PSO, PSA, OR AS: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# SELEXIPAG

## Products Affected

- 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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.  |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST  |
| Coverage Duration            | INITIAL AND RENEWAL: 12 MONTHS   |
| Other Criteria               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. RENEWAL: PATIENT SHOWS IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# SELINEXOR

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## Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 40 MG/WEEK (20 MG X 2), 40MG TWICE WEEK (80 MG/WEEK), 60 MG/WEEK (20 MG X 3), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (20 MG X 4), 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               |                               |

# SELPERCATINIB

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## Products Affected

- RETEVMO ORAL CAPSULE 40 MG,  
80 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SELUMETINIB

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## Products Affected

- KOSELUGO ORAL CAPSULE 10 MG,  
25 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SILTUXIMAB

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## Products Affected

- SYLVANT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SIPONIMOD

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## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 2 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS DEMONSTRATED CLINICAL BENEFIT COMPARED TO PRE TREATMENT BASELINE AND THE PATIENT DOES NOT HAVE LYMPHOPENIA. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SODIUM OXYBATE

## Products Affected

- XYREM

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH ONE OF THE FOLLOWING SPECIALISTS: NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE  |
| <b>Coverage Duration</b>            | INITIAL 6 MONTHS. RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | ALL INDICATIONS: INITIAL: THE PATIENT IS NOT CURRENTLY BEING TREATED WITH SEDATIVE HYPNOTIC AGENTS. EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: THE PATIENT HAS TRIED OR HAS A CONTRAINDICATION TO THE FORMULARY VERSION OF MODAFINIL, ARMODAFINIL OR SOLRIAMFETOL AND ONE OTHER GENERIC STIMULANT INDICATED FOR EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY. RENEWAL: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SOFOSBUVIR

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## Products Affected

- SOVALDI ORAL PELLETS IN PACKET 150 MG, 200 MG
- SOVALDI ORAL TABLET

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | PATIENT WITH END STAGE RENAL DISEASE OR REQUIRES DIALYSIS.  |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL |
| Coverage Duration            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.   |
| Other Criteria               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE.           |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |



# SOFOSBUVIR/VELPATASVIR

## Products Affected

- EPCLUSA
- *sofosbuvir-velpatasvir*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | HCV RNA LEVEL.   |
| Age Restrictions             |  |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH: GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.  |
| Coverage Duration            | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.  |
| Other Criteria               | CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE. HCV RNA LEVEL WITHIN PAST 6 MONTHS. PATIENT IS NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS NOT RECOMMENDED BY THE MANUFACTURER: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, HIV REGIMEN THAT CONTAINS EFAVIRENZ, ROSUVASTATIN AT DOSES ABOVE 10MG, TIPRANA VIR/RITONAVIR OR TOPOTECAN. PATIENTS WITH DECOMPENSATED CIRRHOSIS REQUIRE CONCURRENT RIBAVIRIN UNLESS RIBAVIRIN INELIGIBLE. REQUESTS FOR GENERIC SOFOSBUVIR/VELPATASVIR REQUIRE TRIAL OF OR CONTRAINDICATION TO BRAND EPCLUSA. |
| Indications                  | All FDA-approved Indications.  |

| <b>PA Criteria</b>    | <b>Criteria Details</b> |
|-----------------------|-------------------------|
| <b>Off Label Uses</b> |                         |

# SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

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## Products Affected

- VOSEVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# SOLRIAMFETOL

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## Products Affected

- SUNOSI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| <b>Other Criteria</b>               | EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: THE PATIENT HAS TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL AND ONE OTHER GENERIC STIMULANT INDICATED FOR EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY.<br>OBSTRUCTIVE SLEEP APNEA (OSA): THE PATIENT HAS TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL. RENEWAL: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SOMATROPIN - GROWTH HORMONE

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## Products Affected

- HUMATROPE
- OMNITROPE
- SAIZEN
- SAIZEN SAIZENPREP
- ZOMACTON

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# SOMATROPIN - SEROSTIM

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# SOMATROPIN - ZORBTIVE

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## Products Affected

- ZORBTIVE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES                        |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST |
| <b>Coverage Duration</b>            | SHORT BOWEL: 4 WEEKS ONCE.                                       |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.                                    |
| <b>Off Label Uses</b>               |  |

# SOMATROPIN-NORDITROPIN AND GENOTROPIN

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## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- NORDITROPIN FLEXPPO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |



# SOMATROPIN-NUTROPIN AQ

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## Products Affected

- NUTROPIN AQ NUSPIN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# SONIDEGIB

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## Products Affected

- ODOMZO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | BASELINE SERUM CREATINE KINASE (CK) AND SERUM CREATININE LEVELS |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.                                   |
| <b>Off Label Uses</b>               |   |

# SORAFENIB TOSYLATE

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## Products Affected

- NEXAVAR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# SUNITINIB MALATE

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## Products Affected

- SUTENT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | GASTROINTESTINAL STROMAL TUMORS (GIST): TRIAL OF OR CONTRAINDICATION TO GLEEVEC. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS NOT PROGRESSED TO NYHA CLASS IV HEART FAILURE.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST, ATTR SPECIALIST, OR MEDICAL GENETICIST.  |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PATIENT HAS NEW YORK HEART ASSOCIATION (NYHA) CLASS I, II, OR III HEART FAILURE. DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: 1) BONE SCAN (SCINTIGRAPHY) STRONGLY POSITIVE FOR MYOCARDIAL UPTAKE OF 99MTCYPY/DPD, OR 2) BIOPSY OF TISSUE OF AFFECTED ORGAN(S) (CARDIAC AND POSSIBLY NON-CARDIAC SITES) TO CONFIRM AMYLOID PRESENCE AND CHEMICAL TYPING TO CONFIRM PRESENCE OF TRANSTHYRETIN (TTR) PROTEIN. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TAFASITAMAB-CXIX

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## Products Affected

- MONJUVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TALAZOPARIB

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## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | PATIENT HAS BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING. PATIENTS WITH HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER MUST HAVE ADDITIONAL PRIOR TREATMENT WITH ENDOCRINE THERAPY OR BE CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TALIMOGENE

## Products Affected

- IMLYGIC INJECTION SUSPENSION  
10EXP6 (1 MILLION) PFU/ML, 10EXP8  
(100 MILLION) PFU/ML

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



# TASIMELTEON

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## Products Affected

- HETLIOZ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                              |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | LIFETIME   |
| <b>Other Criteria</b>               | PATIENT IS LIGHT-INSENSITIVE OR HAS TOTAL BLINDNESS. |
| <b>Indications</b>                  | All FDA-approved Indications.                        |
| <b>Off Label Uses</b>               |  |

# TAZEMETOSTAT

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## Products Affected

- TAZVERIK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TEDUGLUTIDE

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## Products Affected

- GATTEX 30-VIAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | PATIENT IS DEPENDENT ON INTRAVENOUS PARENTERAL NUTRITION DEFINED AS REQUIRING PARENTERAL NUTRITION AT LEAST THREE TIMES PER WEEK |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TELOTRISTAT

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## Products Affected

- XERMELO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TEMOZOLOMIDE

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## Products Affected

- TEMODAR INTRAVENOUS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TEPROTUMUMAB-TRBW

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## Products Affected

- TEPEZZA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TERIFLUNOMIDE

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## Products Affected

- AUBAGIO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TERIPARATIDE

## Products Affected

- FORTEO

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | PATIENT HAS RECEIVED A TOTAL OF 24 MONTHS CUMULATIVE TREATMENT WITH ANY PARATHYROID HORMONE THERAPY.   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | ONE OF THE FOLLOWING: (1) HIGH RISK FOR FRACTURES DEFINED AS ONE OF THE FOLLOWING: A) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S), B) 2 OR MORE RISK FACTORS FOR FRACTURE (E.G., HISTORY OF MULTIPLE RECENT LOW TRAUMA FRACTURES, BMD T-SCORE LESS THAN OR EQUAL TO -2.5, CORTICOSTEROID USE, OR USE OF GNRH ANALOGS SUCH AS NAFARELIN, ETC.), C) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR OF AT LEAST 3% FOR HIP FRACTURE. (2) UNABLE TO USE ORAL THERAPY (I.E., UPPER GASTROINTESTINAL PROBLEMS UNABLE TO TOLERATE ORAL MEDICATION, LOWER GASTROINTESTINAL PROBLEMS UNABLE TO ABSORB ORAL MEDICATIONS, TROUBLE REMEMBERING TO TAKE ORAL MEDICATIONS OR COORDINATING AN ORAL BISPHOSPHONATE WITH OTHER ORAL MEDICATIONS OR THEIR DAILY ROUTINE). (3) ADEQUATE TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO BISPHOSPHONATES. |



| <b>PA Criteria</b>    | <b>Criteria Details</b>       |
|-----------------------|-------------------------------|
| <b>Indications</b>    | All FDA-approved Indications. |
| <b>Off Label Uses</b> |                               |

# TESAMORELIN

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## Products Affected

- EGRIFTA SUBCUTANEOUS RECON SOLN 1 MG
- EGRIFTA SV

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 3 MONTHS                      |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TESTOSTERONE

## Products Affected

- *testosterone cypionate intramuscular oil 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*
- *testosterone enanthate*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1%), 20.25 mg/1.25 gram (1.62%)*
- *testosterone transdermal gel in packet 1% (25 mg/2.5gram), 1% (50 mg/5 gram)*
- *testosterone transdermal solution in metered pump w/lapp*
- **XYOSTED**

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: MALE HYPOGONADISM: INITIAL: CONFIRMED BY EITHER: 1) AT LEAST TWO MORNING TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS WHILE IN A FASTED STATE OR 2) A FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 PG/ML.  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | PRIMARY OR SECONDARY HYPOGONADISM: 12 MONTHS. ALL OTHER INDICATIONS: LIFETIME OF MEMBERSHIP IN PLAN.  |
| <b>Other Criteria</b>               | MALE HYPOGONADISM: INITIAL: NO TESTOSTERONE LEVELS ARE REQUIRED WHEN THERE IS A PREVIOUSLY APPROVED AUTHORIZATION FOR TESTOSTERONE OR PATIENT HAS RECEIVED ANY FORM OF TESTOSTERONE REPLACEMENT THERAPY PER PHYSICIAN ATTESTATION OR CLAIMS HISTORY. RENEWAL: PHYSICIAN ATTESTATION OF IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TETRABENAZINE

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## Products Affected

- *tetrabenazine*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                     |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST |
| <b>Coverage Duration</b>            | 12 MONTHS                                   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.               |
| <b>Off Label Uses</b>               |   |

# TEZACAFTOR/IVACAFTOR

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## Products Affected

- SYMDEKO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS.   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: LIFETIME   |
| <b>Other Criteria</b>               | RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# THALIDOMIDE

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## Products Affected

- THALOMID

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TILDRAKIZUMAB

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## Products Affected

- ILUMYA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: PLAQUE PSORIASIS (PSO): MODERATE TO SEVERE PLAQUE PSORIASIS INVOLVING AT LEAST 5% OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.                        |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PSO: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: PSO: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL, SKYRIZI. RENEWAL: PSO: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TOCILIZUMAB IV

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## Products Affected

- ACTEMRA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | MODERATE TO SEVERE RHEUMATOID ARTHRITIS (RA)/POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA)/SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST  |
| Coverage Duration            | INITIAL: RA, PJIA, OR SJIA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: 12 MONTHS FOR RA, PJIA, OR SJIA   |
| Other Criteria               | INITIAL: RA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ. PJIA: PREVIOUS TRIAL OF OR CONTRAINDICATION TO HUMIRA AND ENBREL. RENEWAL FOR RA, PJIA, OR SJIA: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |



# TOCILIZUMAB SQ

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## Products Affected

- ACTEMRA
- ACTEMRA ACTPEN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# TOFACITINIB

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## Products Affected

- XELJANZ
- XELJANZ XR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# TOLVAPTAN

## Products Affected

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLETS, SEQUENTIAL

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | RENEWAL: PHYSICIAN ATTESTATION THAT PATIENT HAS NOT PROGRESSED TO ESRD/DIALYSIS OR TRANSPLANT.  |
| Age Restrictions             |   |
| Prescriber Restrictions      | PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.  |
| Other Criteria               | INITIAL: THE PATIENT MEETS ALL OF THE FOLLOWING: (1) CONFIRMED POLYCYSTIC KIDNEY DISEASE VIA CT, MRI IMAGING, OR ULTRASOUND (2) GENETIC TESTING FOR CAUSATIVE MUTATIONS OR FAMILY HISTORY OF CONFIRMED POLYCYSTIC KIDNEY DISEASE IN ONE OR BOTH PARENTS, AND (3) PATIENT DOES NOT HAVE ESRD (I.E., RECEIVING DIALYSIS OR HAS UNDERGONE RENAL TRANSPLANT). |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TOPICAL TRETINOIN

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## Products Affected

- ALTRENO
- *tretinoin*

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | COSMETIC INDICATIONS SUCH AS WRINKLES, PHOTOAGING, MELASMA.   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | BRAND TOPICAL TRETINOIN REQUIRES TRIAL OF OR CONTRAINDICATION TO A FORMULARY GENERIC TOPICAL TRETINOIN PRODUCT. |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TRABECTEDIN

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## Products Affected

- YONDELIS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TRAMETINIB DIMETHYL SULFOXIDE

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## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | ADJUVANT TREATMENT OF MELANOMA: THE MEDICATION HAS PREVIOUSLY BEEN USED FOR MORE THAN ONE YEAR. |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TRASTUZUMAB

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## Products Affected

- HERCEPTIN INTRAVENOUS RECON SOLN 150 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRASTUZUMAB HYALURONIDASE

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## Products Affected

- HERCEPTIN HYLECTA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |



# TRASTUZUMAB-ANNS

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## Products Affected

- KANJINTI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRASTUZUMAB-DKST

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## Products Affected

- OGIVRI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRASTUZUMAB-DTTB

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## Products Affected

- ONTRUZANT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRASTUZUMAB-PKRB

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## Products Affected

- HERZUMA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRASTUZUMAB-QYYP

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## Products Affected

- TRAZIMERA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 MONTHS  |
| <b>Other Criteria</b>               | THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TREPROSTINIL INHALED

## Products Affected

- TYVASO

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS III-IV SYMPTOMS.  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST  |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. RENEWAL: PATIENT SHOW IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TREPROSTINIL SODIUM INJECTABLE

## Products Affected

- *treprostinil sodium*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION.  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST   |
| <b>Coverage Duration</b>            | INITIAL AND RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               | INITIAL: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG OR GREATER, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS. CONTINUATION OF CURRENT REMODULIN THERAPY: PATIENT MUST HAVE NYHA/WHO FC II-IV SYMPTOMS. NEW REQUESTS FOR REMODULIN THERAPY: PATIENT MUST HAVE NYHA/WHO FC III-IV SYMPTOMS. NEW REQUESTS FOR REMODULIN THERAPY FOR PATIENTS WITH NYHA/WHO FC II SYMPTOMS REQUIRES A TRIAL OF OR CONTRAINDICATION TO A FORMULARY PHOSPHODIESTERASE-5 INHIBITOR OR AN ENDOTHELIN RECEPTOR ANTAGONIST. RENEWAL: PATIENT SHOWS IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR PATIENT HAS A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/ IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |

| <b>PA Criteria</b>    | <b>Criteria Details</b>       |
|-----------------------|-------------------------------|
| <b>Indications</b>    | All FDA-approved Indications. |
| <b>Off Label Uses</b> |                               |



# TRIENTINE

## Products Affected

- *clovique*
- *trientine*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | INITIAL: WILSONS DISEASE: KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE. CONFIRMATION OF ONE OF THE FOLLOWING: 1) PLASMA COPPER-PROTEIN CERULOPLASMIN LESS THAN 20 MG/DL, 2) LIVER BIOPSY POSITIVE FOR AN ABNORMALLY HIGH CONCENTRATION OF COPPER (GREATER THAN 250 MCG/G DRY WEIGHT) OR THE PRESENCE OF KAYSER-FLEISCHER RINGS, OR 3) CONFIRMATION BY GENETIC TESTING FOR ATP7B MUTATIONS. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | WILSONS DISEASE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST.  |
| <b>Coverage Duration</b>            | WILSONS DISEASE: INITIAL AND RENEWAL: 12 MONTHS   |
| <b>Other Criteria</b>               | INITIAL: WILSONS DISEASE: PREVIOUS TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE (DEPEN).<br>RENEWAL: WILSONS DISEASE: CONFIRMED DIAGNOSIS OF WILSONS DISEASE.  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TRIFLURIDINE/TIPIRACIL

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# TUCATINIB

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## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# UPADACITINIB

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## Products Affected

- RINVOQ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | RHEUMATOID ARTHRITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A RHEUMATOLOGIST   |
| Coverage Duration            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.   |
| Other Criteria               | RHEUMATOID ARTHRITIS (RA): INITIAL: PREVIOUS TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RA: RENEWAL: THE PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION. |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# URIDINE TRIACETATE

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## Products Affected

- XURIDEN

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | INITIAL: DIAGNOSIS CONFIRMED BY 1) GENETIC MUTATION OF URIDINE MONOPHOSPHATE SYNTHASE (UMPS) GENE AND 2) ELEVATED URINE OROTIC ACID PER AGE-SPECIFIC REFERENCE RANGE. RENEWAL: IMPROVEMENT FROM BASELINE OR STABILIZATION OF AGE DEPENDENT HEMATOLOGIC PARAMETERS (E.G., NEUTROPHIL COUNT, NEUTROPHIL PERCENT, WBC COUNT, MEAN CORPUSCULAR VOLUME) |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES  |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS  |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# USTEKINUMAB

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## Products Affected

- STELARA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>           |
|-------------------------------------|-----------------------------------|
| <b>Exclusion Criteria</b>           | PA Criteria: Pending CMS Approval |
| <b>Required Medical Information</b> | PA Criteria: Pending CMS Approval |
| <b>Age Restrictions</b>             | PA Criteria: Pending CMS Approval |
| <b>Prescriber Restrictions</b>      | PA Criteria: Pending CMS Approval |
| <b>Coverage Duration</b>            | PA Criteria: Pending CMS Approval |
| <b>Other Criteria</b>               | PA Criteria: Pending CMS Approval |
| <b>Indications</b>                  | PA Criteria: Pending CMS Approval |
| <b>Off Label Uses</b>               | PA Criteria: Pending CMS Approval |

# USTEKINUMAB IV

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## Products Affected

- STELARA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | CROHNS DISEASE (CD) AND ULCERATIVE COLITIS: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A GASTROENTEROLOGIST.  |
| <b>Coverage Duration</b>            | 2 MONTHS   |
| <b>Other Criteria</b>               | CROHNS DISEASE (CD) AND ULCERATIVE COLITIS: PREVIOUS TRIAL OF OR CONTRAINDICATION TO AT LEAST ONE CONVENTIONAL THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# VALBENZINE

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## Products Affected

- INGREZZA
- INGREZZA INITIATION PACK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST. |
| <b>Coverage Duration</b>            | 12 MONTHS   |
| <b>Other Criteria</b>               | TARDIVE DYSKINESIA: PATIENT HAS A PRIOR HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA             |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |



# VANDETANIB

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG,  
300 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# VEMURAFENIB

---

## Products Affected

- ZELBORAF

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# VENETOCLAX

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## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# VESTRONIDASE ALFA VJBK

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## Products Affected

- MEPSEVII

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | RENEWAL: PHYSICIAN ATTESTATION THAT THE PATIENT HAS IMPROVED, MAINTAINED, OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY FROM BASELINE. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN GENETIC OR METABOLIC DISORDERS.   |
| <b>Coverage Duration</b>            | INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS   |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>INITIAL: THE PATIENT MEETS ALL OF THE FOLLOWING CRITERIA: 1) THE PATIENT HAS NOT UNDERGONE SUCCESSFUL BONE MARROW OR STEM CELL TREATMENT FOR MPS VII, 2) THE PATIENT HAS LIMITATION IN MOBILITY, BUT REMAINS SUFFICIENTLY AMBUATLORY, AND 3) DIAGNOSIS OF MPS VII CONFIRMED BY ALL OF THE FOLLOWING CRITERIA: A) PHYSICIAN ATTESTATION OF URINARY GAG (GLYCOSAMINOGLYCAN) LEVEL OF GREATER THAN THREE TIMES THE UPPER LEVEL OF NORMAL BASED ON THE LABORATORY ASSAY, B) PHYSICIAN ATTESTATION OF BETA-GLUCURONIDASE ENZYME ACTIVITY DEFICIENCY OR GENETIC TESTING, AND C) PHYSICIAN ATTESTATION THAT THE PATIENT HAS AT LEAST ONE OF THE FOLLOWING CLINICAL SIGNS OF MPS VII: ENLARGED LIVER AND SPLEEN, JOINT LIMITATIONS, AIRWAY OBSTRUCTIONS OR PULMONARY DYSFUNCTION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p> |
| <b>Indications</b>    | All FDA-approved Indications.   |
| <b>Off Label Uses</b> |   |

# VIGABATRIN

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## Products Affected

- *vigabatrin*
- *vigadrone*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROLOGIST   |
| Coverage Duration            | 12 MONTHS   |
| Other Criteria               | REFRACTORY COMPLEX PARTIAL SEIZURES (CPS): PATIENT HAS RESPONDED INADEQUATELY TO AT LEAST 2 ANTIEPILEPTIC AGENTS. FOR CPS AND INFANTILE SPASMS: PHYSICIAN ATTESTATION THAT BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# VISMODEGIB

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## Products Affected

- ERIVEDGE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |

# ZANUBRUTINIB

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## Products Affected

- BRUKINSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Exclusion Criteria</b>           |                               |
| <b>Required Medical Information</b> |                               |
| <b>Age Restrictions</b>             |                               |
| <b>Prescriber Restrictions</b>      |                               |
| <b>Coverage Duration</b>            | 12 MONTHS                     |
| <b>Other Criteria</b>               |                               |
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off Label Uses</b>               |                               |





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