

# 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

# 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

- *abiraterone oral tablet 250 mg*
- ZYTIGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.
Indications	All FDA-approved Indications.
Off Label Uses	

# ABIRATERONE SUBMICRONIZED

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## Products Affected

- YONSA

<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>	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: PHYSICIAN ATTESTATION THAT THE PATIENT CANNOT USE THE FORMULARY PREFERRED AGENT ZYTIGA (ABIRATERONE ACETATE) AND ONE OF THE FOLLOWING: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: PLAQUE PSORIASIS (PSO): 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>	RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), ANKYLOSING SPONDYLITIS (AS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. UVEITIS: PRESCRIBED BY OR IN CONSULTATION WITH AN OPHTHALMOLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

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

# 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>	INITIAL: FABRY DISEASE: 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>	FABRY DISEASE: PRESCRIBED BY OR 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: INITIAL: PATIENT IS NOT CONCURRENTLY USING AN ALPHA-GAL A PHARMACOLOGICAL CHAPERONE (I.E., GALAFOLD (MIGALASTAT)), RENEWAL: 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>	

# 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)

<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>	

# AMIVANTAMAB-VMJW

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## Products Affected

- RYBREVANT

<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>	

# 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): PATIENT HAS HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). NMCRPC OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: DIAGNOSIS OF NMCRPC OR MCSPC.
Indications	All FDA-approved Indications.
Off Label Uses	

# APOMORPHINE

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## Products Affected

- APOKYN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	PARKINSONS DISEASE (PD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PD: INITIAL: PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: PATIENT HAD IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF APOKYN.
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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 YEARS OR OLDER
Prescriber Restrictions	PARKINSONS DISEASE (PD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PD: PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: PD: PATIENT IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF KYNMOBI.
Indications	All FDA-approved Indications.
Off Label Uses	

# 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

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## Products Affected

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

# 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>	

# 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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. LUPUS NEPHRITIS (LN): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: SLE: CURRENTLY TAKING CORTICOSTEROIDS, ANTIMALARIALS, NSAIDS, OR IMMUNOSUPPRESSIVE AGENTS. RENEWAL: SLE: PATIENT HAD CLINICAL IMPROVEMENT. LN: CLINICAL IMPROVEMENT IN RENAL RESPONSE COMPARED TO BASELINE OR CLINICAL PARAMETERS (E.G., FLUID RETENTION, USE OF RESCUE DRUGS, GLUCOCORTICOID DOSE).
Indications	All FDA-approved Indications.
Off Label Uses	

# 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>	

# BELUMOSUDIL MESYLATE

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## Products Affected

- REZUROCK

<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

# BELZUTIFAN

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## Products Affected

- WELIREG

<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>	



# BENDAMUSTINE

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## Products Affected

- BENDEKA
- TREANDA

<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
Exclusion Criteria	
Required Medical Information	INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	
Prescriber Restrictions	ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	12 MONTHS
Other Criteria	ASTHMA: 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), AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS. RENEWAL: 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>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# BEROTRALSTAT

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## Products Affected

- ORLADEYO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: HEREDITARY ANGIOEDEMA (HAE); DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST, IMMUNOLOGIST, OR HEMATOLOGIST.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE, RENEWAL: IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY).
<b>Indications</b>	All FDA-approved Indications.
<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>	TRIAL OF OR CONTRAINIDCATION TO ZIRABEV WHERE INDICATIONS ALIGN. 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>	

# 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>	TRIAL OF OR CONTRAINDICATION TO ZIRABEV WHERE INDICATIONS ALIGN. 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>	

# 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>	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>	

# 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. MRD-POSITIVE B-CELL: 2 MOS. RENEWAL: 12 MOS.

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	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>	

# 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>	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>	

# 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>	

# C1 ESTERASE INHIBITOR-CINRYZE, BERINERT

## Products Affected

- CINRYZE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: HEREDITARY ANGIOEDEMA (HAE); DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	HAE: CINRYZE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE. RENEWAL: IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY). 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>	INITIAL: HEREDITARY ANGIOEDEMA (HAE): DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	HAE: HAEGARDA: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE. RENEWAL: IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY).
<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>	

# CALASPARGASE PEGOL-MKNL

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## Products Affected

- ASPARLAS

<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)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS), SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA), ADULT-ONSET STILLS DISEASE (AOSD): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR AN IMMUNOLOGIST.
<b>Coverage Duration</b>	INITIAL:AOSD, SJIA:6 MONTHS. INITIAL:ALL OTHER INDICATIONS:12 MONTHS. RENEWAL:AOSD, SJIA:12 MONTHS.
<b>Other Criteria</b>	INITIAL: AOSD, SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUGS). RENEWAL: AOSD, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.
<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>	DRAVET SYNDROME (DS), LENNOX-GASTAUT SYNDROME (LGS), TUBEROUS SCLEROSIS COMPLEX (TSC): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	INITIAL: 12 MONTHS. RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	INITIAL: LENNOX-GASTAUT SYNDROME (LGS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CLOBAZAM, TOPIRAMATE, LAMOTRIGINE. RENEWAL: DS, LGS, TSC: CONFIRMATION OF DIAGNOSIS.
<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>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	CABLIVI WAS PREVIOUSLY INITIATED AS PART OF THE FDA APPROVED TREATMENT REGIMEN IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY WITHIN AN INPATIENT SETTING. THE PATIENT HAS NOT EXPERIENCED MORE THAN TWO RECURRENCES OF ATTP WHILE ON CABLIVI THERAPY (I.E., NEW DROP IN PLATELET COUNT REQUIRING REPEAT PLASMA EXCHANGE DURING 30 DAYS POST-PLASMA EXCHANGE THERAPY [PEX] AND UP TO 28 DAYS OF EXTENDED THERAPY).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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>	

# CETUXIMAB

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## Products Affected

- ERBITUX

<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>	

# 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*

<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>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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>	LENNOX-GASTAUT SYNDROME (LGS): 1) PATIENT IS UNABLE TO TAKE TABLETS OR SUSPENSION AND 2) 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>	

# CYSTEAMINE HYDROCHLORIDE

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## Products Affected

- CYSTARAN

<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*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	MULTIPLE SCLEROSIS (MM): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	MM: INITIAL: WALKING DISABILITY SUCH AS MILD TO MODERATE BILATERAL LOWER EXTREMITY WEAKNESS OR UNILATERAL WEAKNESS PLUS LOWER EXTREMITY OR TRUNCAL ATAXIA. RENEWAL: IMPROVEMENT IN WALKING ABILITY.
Indications	All FDA-approved Indications.
Off Label Uses	



# 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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (NMCRPC): PATIENT HAS HIGH RISK PROSTATE CANCER (I.E., RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS) AND ONE OF THE FOLLOWING: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: DIAGNOSIS OF NMCRPC.
Indications	All FDA-approved Indications.
Off Label Uses	

# 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>	
<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>	

# DEFERASIROX

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## Products Affected

- *deferasirox*

<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

# DEFERIPRONE

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## Products Affected

- *deferiprone* MG
- FERRIPROX 1,000 MG TAB(2X/DAY)
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1,000

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

# DEFEROXAMINE

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## Products Affected

- *deferoxamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	CHRONIC IRON OVERLOAD: AT LEAST 3 YEARS OF AGE OR OLDER
Prescriber Restrictions	CHRONIC IRON OVERLOAD: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	



# 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	DUCHENNE MUSCULAR DYSTROPHY (DMD): DIAGNOSIS CONFIRMED BY GENETIC TESTING.
Age Restrictions	
Prescriber Restrictions	DMD: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: 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: A) PATIENT IS NOT IN STAGE 1 (PRE-SYMPTOMATIC PHASE), B) STEROID MYOPATHY HAS BEEN RULED OUT, C) DETERIORATION IN AMBULATION, FUNCTIONAL STATUS, OR PULMONARY FUNCTION CONSISTENT WITH ADVANCING DISEASE. RENEWAL: 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>	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

# 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	
Age Restrictions	
Prescriber Restrictions	HUNTINGTON DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST. TARDIVE DYSKINESIA: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST.
Coverage Duration	12 MONTHS
Other Criteria	TARDIVE DYSKINESIA: PRIOR HISTORY OF USING ANTIPSYCHOTIC MEDICATIONS OR METOCLOPRAMIDE.
Indications	All FDA-approved Indications.
Off Label Uses	

# DICHLORPHENAMIDE

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## Products Affected

- KEVEYIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 YEARS AND OLDER
<b>Prescriber Restrictions</b>	PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	INITIAL: 2 MONTHS, RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	INITIAL: PATIENT DOES NOT HAVE HEPATIC INSUFFICIENCY, PULMONARY OBSTRUCTION, OR A HEALTH CONDITION THAT WARRANTS CONCURRENT USE OF HIGH-DOSE ASPIRIN. RENEWAL: IMPROVEMENT IN SYMPTOMS.
<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

<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

# DIMETHYL FUMARATE

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## Products Affected

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

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



# 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>	

# DOSTARLIMAB-GXLY

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## Products Affected

- JEMPERLI

<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

- *droxidopa*

<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

# 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

- ORILISSA 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 PREPARATION. 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>	

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	ITP: 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	INITIAL: CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA PURPURA (ITP): TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. ALL INDICATIONS: APPROVAL FOR PROMACTA ORAL SUSPENSION PACKETS REQUIRES A TRIAL OF PROMACTA TABLETS OR PATIENT IS UNABLE TO TAKE TABLET FORMULATION. ITP: RENEWAL: PATIENT HAS SHOWN A CLINICAL RESPONSE.
Indications	All FDA-approved Indications.
Off Label Uses	



# EMAPALUMAB-LZSG

## Products Affected

- GAMIFANT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>INITIAL: HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH): PATIENT HAS UNDERGONE A GENETIC TEST IDENTIFYING HLH-ASSOCIATED GENE MUTATION (E.G., PRF1, UNC13D) OR PATIENT HAS AT LEAST FIVE OF THE FOLLOWING EIGHT DIAGNOSTIC CRITERIA FOR HLH: 1) FEVER, 2) SPLENOMEGALY, 3) CYTOPENIAS (AFFECTING AT LEAST 2 OF 3 CELL LINEAGES), 4) HYPERTRIGLYCERIDEMIA OR HYPOFIBRINOGENEMIA, 5) HEMOPHAGOCYTOSIS IN BONE MARROW OR SPLEEN OR LYMPH NODES AND NO EVIDENCE OF MALIGNANCY, 6) LOW OR ABSENT NATURAL KILLER-CELL ACTIVITY, 7) FERRITIN LEVEL OF 500 MCG/L OR GREATER, 8) SOLUBLE CD25 LEVEL OF 2,400 U/ML OR GREATER.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HLH: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH AN IMMUNOLOGIST, HEMATOLOGIST, OR ONCOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 8 WEEKS.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>INITIAL: HLH: 1) CONCURRENT THERAPY WITH DEXAMETHASONE AND 2) PATIENT EITHER HAS REFRACTORY, RECURRENT, OR PROGRESSIVE DISEASE, OR HAD A TRIAL OF OR INTOLERANCE TO CONVENTIONAL HLH THERAPY (I.E., CHEMOTHERAPY, STEROIDS, IMMUNOTHERAPY). RENEWAL: HLH: 1) PATIENT HAS NOT RECEIVED SUCCESSFUL HEMATOPOIETIC STEM CELL TRANSPLANTATION AND 2) PATIENT HAS DEMONSTRATED IMPROVED IMMUNE SYSTEM RESPONSE FROM BASELINE (E.G., RESOLUTION OF FEVER, DECREASED SPLENOMEGALY, IMPROVEMENT IN CNS SYMPTOMS, IMPROVED CBC, INCREASED FIBRINOGEN LEVELS, REDUCED D-DIMER, REDUCED FERRITIN, REDUCED SOLUBLE CD25 LEVELS.)</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	INITIAL: CASTRATION-RESISTANT PROSTATE CANCER (CRPC) THAT IS NOT METASTATIC: PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: DIAGNOSIS OF CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR MCSPC.
Indications	All FDA-approved Indications.
Off Label Uses	

# 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>	

# 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>	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

# 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,  
20,000 UNIT/2 ML, 20,000 UNIT/ML,  
3,000 UNIT/ML, 4,000 UNIT/ML, 40,000  
UNIT/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE THERAPY, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL OF LESS THAN 10G/DL. ELECTIVE NON-CARDIAC OR NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL LESS THAN 13G/DL. RENEWAL: CKD: 1) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR 2) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND DOSE REDUCTION/INTERRUPTION IS REQUIRED TO REDUCE THE NEED FOR BLOOD TRANSFUSIONS. ANEMIA RELATED TO ZIDOVUDINE THERAPY: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. CANCER CHEMOTHERAPY: 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.

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

# ESKETAMINE

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## Products Affected

- SPRAVATO

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



# ETANERCEPT

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## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE OR GENITAL AREA.
Age Restrictions	RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), PSORIATIC ARTHRITIS (PSA): 18 YEARS OR OLDER.
Prescriber Restrictions	RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), AS: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. PJIA, PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. RENEWAL: RA, PJIA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# ETEPLIRSEN

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## Products Affected

- EXONDYS-51

<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>	DMD: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	DMD: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	DMD: INITIAL: PATIENT IS AMBULATORY AND IS CURRENTLY RECEIVING TREATMENT WITH OR HAS A CONTRAINDICATION TO CORTICOSTEROIDS, RENEWAL: MAINTAINED OR DEMONSTRATED A LESS THAN EXPECTED DECLINE IN AMBULATORY ABILITY IN MUSCLE FUNCTION ASSESSMENTS OR OTHER MUSCLE FUNCTION. 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
- *everolimus (antineoplastic)*

<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>	

# 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

<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

# FENFLURAMINE

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## Products Affected

- FINTEPLA

<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.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	RENEWAL: PATIENT HAS SHOWN CONTINUED CLINICAL BENEFIT (E.G. REDUCTION OF SEIZURES, REDUCED LENGTH OF SEIZURES, SEIZURE CONTROL MAINTAINED)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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

- NIVESTYM
- ZARXIO

<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

# 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>	

# GALCANEZUMAB-GNLM

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## 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	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

# 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
- *glatopra subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatiramer 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	

# GLYCEROL PHENYL BUTYRATE

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## Products Affected

- RAVICTI

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

# GUSELKUMAB

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: PLAQUE PSORIASIS (PSO): 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>	PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
<b>Other Criteria</b>	INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). PSO: TRIAL OF OR CONTRAINDICATION ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. RENEWAL: PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH CONCENTRATION ORAL OPIOID SOLUTIONS

## Products Affected

- *morphine concentrate oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	OPIOID TOLERANT: 12 MONTHS. HOSPICE, PALLIATIVE CARE OR END OF LIFE CARE: LIFETIME.
Other Criteria	1) OPIOID TOLERANT (I.E. PREVIOUS USE OF 60 MG ORAL MORPHINE PER DAY, 25 MCG TRANSDERMAL FENTANYL PER HOUR, 30 MG ORAL OXYCODONE PER DAY, 8 MG ORAL HYDROMORPHONE PER DAY, 25 MG ORAL OXYMORPHONE PER DAY, 60 MG ORAL HYDROCODONE PER DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID) AND HAS TROUBLE SWALLOWING OPIOID TABLETS, CAPSULES, OR LARGE VOLUMES OF LIQUID, OR 2) ENROLLED IN HOSPICE OR PALLIATIVE CARE OR END OF LIFE CARE.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - PROMETHAZINE

## Products Affected

- *promethazine injection solution* mg
- *promethazine oral*
- *promethazine rectal suppository 50 mg*
- *promethegan rectal suppository 12.5 mg, 25*

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

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



# HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - SCOPOLAMINE

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## Products Affected

- *scopolamine base*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS REQUIRE PHYSICIAN ATTESTATION THAT REQUESTED MEDICATION IS USED TO TREAT A DIAGNOSIS UNRELATED TO THE TERMINAL ILLNESS OR RELATED CONDITION, AND ARE APPROVED WITHOUT REQUIRING PRESCRIBER ACKNOWLEDGEMENT.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH RISK DRUGS IN THE ELDERLY - BARBITURATE COMBINATIONS

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## Products Affected

- *butalbital-acetaminophen-caff oral tablet*
- *butalbital-aspirin-caffeine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY - DIPYRIDAMOLE

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## Products Affected

- *dipyridamole oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY - DISOPYRAMIDE

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## Products Affected

- *disopyramide phosphate oral capsule*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH RISK DRUGS IN THE ELDERLY - ENDOCRINE - ESTROGEN

## Products Affected

- *amabelz*
- *dotti*
- DUAVEE
- *estradiol oral*
- *estradiol transdermal patch semiweekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet oral tablet 0.5-0.1 mg*
- *fyavolv*
- *jinteli*
- *lyllana*
- *mimvey*
- *norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg*
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. ALL OTHER FDA APPROVED INDICATIONS NOT PREVIOUSLY MENTIONED IN THIS SECTION, SUCH AS PALLIATIVE TREATMENT, AND HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH RISK DRUGS IN THE ELDERLY - ENDOCRINE - SULFONYLUREAS

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	TRIAL OF GLIMEPIRIDE, GLIPIZIDE, OR PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS ARE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY - KETOROLAC

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## Products Affected

- *ketorolac oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	30 DAYS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY - SKELETAL MUSCLE RELAXANTS

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED A HIGH RISK MEDICATION FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	



# HIGH RISK DRUGS IN THE ELDERLY

## ANTICHOLINERGICS -

### CYPROHEPTADINE\_CARBINOXAMINE

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#### Products Affected

- *cyproheptadine oral syrup*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY- ANTICHOLINERGICS- DIPHENHYDRAMINE ELIXIR

## Products Affected

- *diphenhydramine hcl oral elixir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ANTIHISTAMINIC CONDITIONS (PRURITUS OR URTICARIA): TRIAL OR CONTRAINDICATION TO A NON-SEDATING ANTIHISTAMINE SUCH AS LEVOCETIRIZINE. INSOMNIA: TRIAL OF SILENOR AND BELSOMRA. MOTION SICKNESS AND ANTIPARKINSONISM: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED AS HIGH RISK MEDICATION IN THE ELDERLY FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS AND ANAPHYLACTIC REACTIONS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY- DIPHENOXYLATE-ATROPINE

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## Products Affected

- *diphenoxylate-atropine oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH RISK DRUGS IN THE ELDERLY- INDOMETHACIN

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## Products Affected

- *indomethacin oral capsule 25 mg, 50 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# HIGH RISK DRUGS IN THE ELDERLY- MEGESTROL

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK DRUGS IN THE ELDERLY- PAROXETINE

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## Products Affected

- *paroxetine hcl oral tablet*
- PAXIL ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# HIGH RISK MEDICATIONS IN THE ELDERLY- PHENOBARBITAL

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## Products Affected

- *phenobarbital*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	FOR TREATMENT OF EPILEPSY/SEIZURES IN PATIENTS WHO ARE NEWLY PRESCRIBED PHENOBARBITAL: PATIENT HAS NOT RESPONDED TO AT LEAST ONE ANTICONVULSANT OR PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. HOSPICE PATIENTS WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	

# 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*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 36 MONTHS. ALL OTHER DIAGNOSES: 12 MONTHS.
Other Criteria	PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA: PATIENT HAS NOT RECEIVED A PREVIOUS TREATMENT WITH ANOTHER TYROSINE KINASE INHIBITOR.
Indications	All FDA-approved Indications.
Off Label Uses	

# INFIGRATINIB

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## Products Affected

- TRUSELTIQ

<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>	

# INOTUZUMAB OZOGAMICIN

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## Products Affected

- BESPONSE

<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- AVONEX, BETASERON, PLEGRIDY

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## Products Affected

- 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

PA Criteria	Criteria 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

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

# 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>	

# 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>	INITIAL: HEREDITARY ANGIOEDEMA (HAE); DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HAE: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIST/IMMUNOLOGIST OR HEMATOLOGIST.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE, RENEWAL: IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# LANREOTIDE

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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

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## Products Affected

- *lapatinib*

<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: TRIAL OF VITRAKVI CAPSULES OR PATIENT IS UNABLE TO TAKE CAPSULE FORMULATION.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# LEDIPASVIR-SOFOSBUVIR

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## Products Affected

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

# 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

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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>	THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 28 POST TRANSPLANTATION AND PATIENT IS NOT RECEIVING THE MEDICATION BEYOND 100 DAYS POST TRANSPLANTATION.
<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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PARKINSONS DISEASE (PD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	PD: INITIAL: 1) PATIENT IS NOT CURRENTLY TAKING MORE THAN 1600MG OF LEVODOPA PER DAY, AND 2) PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: PATIENT HAD IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF INBRIJA.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# L-GLUTAMINE

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## Products Affected

- ENDARI

<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>	SICKLE CELL DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST.
<b>Coverage Duration</b>	INITIAL: 12 MONTHS. RENEWAL: LIFETIME.
<b>Other Criteria</b>	INITIAL: PATIENTS 18 YEARS OR OLDER: 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. PATIENTS 5 TO 17 YEARS: APPROVED WITHOUT ADDITIONAL CRITERIA. RENEWAL: PATIENT HAS MAINTAINED OR EXPERIENCED REDUCTION IN ACUTE COMPLICATIONS OF SICKLE CELL DISEASE.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	



# 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**

<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

# LIDOCAINE PRILOCAINE

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## 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

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## 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>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST.
<b>Coverage Duration</b>	12 MONTHS

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>1) DIAGNOSIS DETERMINED BY A) DEFINITE SIMON BROOME DIAGNOSTIC CRITERIA, OR B) DUTCH LIPID NETWORK CRITERIA SCORE OF 8 OR GREATER, OR C) CLINICAL DIAGNOSIS BASED ON A HISTORY OF AN UNTREATED LDL-C CONCENTRATION GREATER THAN 500 MG/DL TOGETHER WITH EITHER XANTHOMA BEFORE 10 YEARS OF AGE, OR EVIDENCE OF HEFH IN BOTH PARENTS. 2) LDL-C LEVEL GREATER THAN OR EQUAL TO 70MG/DL WHILE ON MAXIMAL DRUG TREATMENT. 3) TRIAL OF EVOLOCUMAB UNLESS THE PATIENT HAS NON-FUNCTIONING LDL RECEPTORS. 4) MEETS ONE OF THE FOLLOWING: A) TAKING A HIGH-INTENSITY STATIN (I.E., ATORVASTATIN 40-80MG DAILY, ROSUVASTATIN 20-40MG DAILY) FOR A DURATION OF AT LEAST 8 WEEKS, B) TAKING A MAXIMALLY TOLERATED DOSE OF ANY STATIN FOR A DURATION OF AT LEAST 8 WEEKS GIVEN THAT THE PATIENT CANNOT TOLERATE A HIGH-INTENSITY STATIN, C) ABSOLUTE CONTRAINDICATION TO STATIN THERAPY (E.G., ACTIVE DECOMPENSATED LIVER DISEASE, NURSING FEMALE, PREGNANCY OR PLANS TO BECOME PREGNANT, HYPERSENSITIVITY REACTIONS), D) STATIN INTOLERANCE, OR E) TRIAL OF ROSUVASTATIN, ATORVASTATIN, OR STATIN THERAPY AT ANY DOSE AND HAS EXPERIENCED SKELETAL-MUSCLE RELATED SYMPTOMS (E.G., MYOPATHY).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# LONCASTUXIMAB TESIRINE-LPYL

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## Products Affected

- ZYNLONTA

<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>	

# LORLATINIB

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## 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>	

# LUMACAF TOR-IVACAF TOR

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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>	INITIAL: CYSTIC FIBROSIS (CF): CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CF.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CF EXPERT.
<b>Coverage Duration</b>	CF: INITIAL: 6 MONTHS, RENEWAL: LIFETIME.
<b>Other Criteria</b>	RENEWAL: CF: PATIENT 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>	

# LUMASIRAN

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## Products Affected

- OXLUMO

<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>	



# 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>	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

# MELPHALAN FLUFENAMIDE HCL

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## Products Affected

- PEPAXTO

<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>	
<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>	ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN PULMONARY OR ALLERGY MEDICINE.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	ASTHMA: 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 ASTHMA-RELATED EVENT REQUIRING HOSPITALIZATION, EMERGENCY ROOM VISIT, OR SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS), AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS, RENEWAL: 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>PA Criteria</b>	<b>Criteria Details</b>
<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

## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: CUSHINGS SYNDROME (CS): DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: 1) 24-HR URINE FREE CORTISOL (2 OR MORE TESTS TO CONFIRM), 2) OVERNIGHT 1MG DEXAMETHASONE TEST, OR 3) LATE NIGHT SALIVARY CORTISOL (2 OR MORE TESTS TO CONFIRM).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	CS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	CD: INITIAL: HYPERCORTISOLISM IS NOT A RESULT OF CHRONIC GLUCOCORTICOIDS, RENEWAL: 1) PATIENT CONTINUES TO HAVE IMPROVEMENT OF GLUCOSE TOLERANCE OR STABLE GLUCOSE TOLERANCE (E.G., REDUCED A1C, IMPROVED FASTING GLUCOSE, ETC.), 2) PATIENT CONTINUES TO HAVE TOLERABILITY TO KORLYM, AND 3) PATIENT CONTINUES TO NOT BE A CANDIDATE FOR SURGICAL TREATMENT OR HAS FAILED SURGERY.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# MIGALASTAT

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## Products Affected

- GALAFOLD

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

# NAXITAMAB-GQGK

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## Products Affected

- DANYELZA

<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>	

# 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>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	EARLY-STAGE TUMOR (STAGE I-III) AND THE MEDICATION IS BEING REQUESTED WITHIN 2 YEARS OF COMPLETING THE LAST TRASTUZUMAB DOSE. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	



# 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, F359V/C/I, OR G250E.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# NINTEDANIB

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	<p>INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): NOT APPROVED FOR PATIENTS WITH OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, OR CANCER). SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): NOT APPROVED FOR PATIENTS WITH OTHER KNOWN CAUSES OF ILD [E.G., HEART FAILURE/FLUID OVERLOAD, DRUG-INDUCED LUNG TOXICITY (CYCLOPHOSPHAMIDE, METHOTREXATE, ACE-INHIBITORS), RECURRENT ASPIRATION (SUCH AS FROM GERD), PULMONARY VASCULAR DISEASE, PULMONARY EDEMA, PNEUMONIA, CHRONIC PULMONARY THROMBOEMBOLISM, ALVEOLAR HEMORRHAGE OR ILD CAUSED BY ANOTHER RHEUMATIC DISEASE, SUCH AS MIXED CONNECTIVE TISSUE DISEASE (MCTD)].</p>
<b>Required Medical Information</b>	<p>INITIAL: IPF: 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) BASELINE FORCED VITAL CAPACITY (FVC) AT LEAST 50% OF PREDICTED VALUE. SSC-ILD: AT LEAST 10% FIBROSIS ON A CHEST HRCT AND BASELINE FVC AT LEAST 40% OF PREDICTED VALUE. PF-ILD: AT LEAST 10% FIBROSIS ON A CHEST HRCT AND BASELINE FVC AT LEAST 45% OF PREDICTED VALUE.</p>
<b>Age Restrictions</b>	<p>INITIAL: IPF, SSC-ILD, PF-ILD: 18 YEARS OR OLDER.</p>

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.
<b>Coverage Duration</b>	INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL: 12 MOS.
<b>Other Criteria</b>	INITIAL: IPF: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ESBRIET. SSC-ILD: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ACTEMRA SUBQ. PF-ILD: LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENERD/PROGRESSED DESPITE TREATMENT WITH MEDICATIONS USED IN CLINICAL PRACTICE FOR ILD (NOT ATTRIBUTABLE TO COMORBIDITIES SUCH AS INFECTION, HEART FAILURE). RENEWAL: IPF, SSC-ILD, PF-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# NIRAPARIB

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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>	RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: ZEJULA WILL BE USED AS MONOTHERAPY AND IS STARTED NO LATER THAN 8 WEEKS AFTER THE MOST RECENT PLATINUM-CONTAINING REGIMEN.
<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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: HEREDITARY TYROSINEMIA TYPE 1 (HT-1); DIAGNOSIS CONFIRMED BY ELEVATED URINARY OR PLASMA SUCCINYLACETONE LEVELS OR A MUTATION IN THE FUMARYLACETOACETATE HYDROLASE GENE.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	HT-1: PRESCRIBED BY OR IN CONSULTATION WITH A PRESCRIBER SPECIALIZING IN INHERITED METABOLIC DISEASES.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	HT-1: INITIAL: ORFADIN SUSPENSION: TRIAL OF OR CONTRAINDICATION TO PREFERRED FORMULARY NITISINONE TABLETS OR CAPSULES, RENEWAL: URINARY OR PLASMA SUCCINYLACETONE LEVELS HAVE DECREASED FROM BASELINE WHILE ON TREATMENT WITH NITISINONE.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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

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## Products Affected

- OCALIVA

<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

# 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>	



# OFATUMUMAB-SQ

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## Products Affected

- KESIMPTA 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>	
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# OLAPARIB

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## Products Affected

- LYNPARZA

<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

## Products Affected

- SYNRIBO

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

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: 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.
Age Restrictions	
Prescriber Restrictions	INITIAL AND RENEWAL: CHRONIC IDIOPATHIC URTICARIA (CIU): PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE, DERMATOLOGY OR IMMUNOLOGY. INITIAL: NASAL POLYPS: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST. ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	INITIAL: ASTHMA: 12 MO. CIU, NASAL POLYPS: 6 MO. RENEWAL: ASTHMA, NASAL POLYPS: 12 MO. CIU: 6 MO.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>INITIAL: CIU: TRIAL OF OR CONTRAINDICATION TO A MAXIMALLY TOLERATED DOSE OF AN H1 ANTI-HISTAMINE AND STILL EXPERIENCES HIVES ON MOST DAYS OF THE WEEK. NASAL POLYPS: PREVIOUS 90 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID. 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) 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, AND 4) NOT CONCURRENTLY RECEIVING DUPIXENT OR OTHER ANTI-IL5 BIOLOGIC. RENEWAL: CIU: DIAGNOSIS OF CIU. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE. ASTHMA: 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>	

# OSIMERTINIB

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## Products Affected

- TAGRISSO

<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>	METASTATIC NSCLC WITH EGFR T790M MUTATION: PATIENT IS NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR.
<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>	

# 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

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## Products Affected

- SYNAGIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	CUSHINGS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	RENEWAL: CD: PATIENT CONTINUES TO HAVE IMPROVEMENT OF CD AND MAINTAINS TOLERABILITY TO SIGNIFOR.
<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>	
<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>	PAH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS
<b>Other Criteria</b>	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) MEAN PULMONARY ARTERY PRESSURE (PAP) 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: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	
<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>	PAH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS
<b>Other Criteria</b>	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) MEAN PULMONARY ARTERY PRESSURE (PAP) 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: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR 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

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## Products Affected

- FULPHILA
- NEULASTA
- NYVEPRIA
- UDENYCA

<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

# PEGVALIASE-PQPZ

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## Products Affected

- PALYNZIQ

<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

# 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

<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

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## Products Affected

- *penicillamine*
- THIOLA EC

<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

# PERTUZUMAB-TRASTUZUMAB-HY-ZZXF

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## Products Affected

- PHESGO SUBCUTANEOUS  
SOLUTION 1,200 MG-600MG- 30000  
UNIT/15ML, 600 MG-600 MG- 20000  
UNIT/10ML

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

# 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

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): PATIENTS WITH KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, OR CANCER).
<b>Required Medical Information</b>	INITIAL: IPF: 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) BASELINE FORCED VITAL CAPACITY (FVC) AT LEAST 50% OF PREDICTED VALUE.
<b>Age Restrictions</b>	IPF: 18 YEARS OR OLDER.
<b>Prescriber Restrictions</b>	IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.
<b>Coverage Duration</b>	IPF: INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	RENEWAL: IPF: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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

<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>	

# POSACONAZOLE

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## Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole oral tablet, delayed release (drlec)*

<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

# 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	

# QUININE SULFATE

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## Products Affected

- *quinine sulfate*

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

# 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>	

# RELUGOLIX

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## Products Affected

- ORGOVYX

<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>	
<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>	ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	ASTHMA: 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), AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS, RENEWAL: 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>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<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/HE: 12 MOS. IBS-D: 12 WKS.
<b>Other Criteria</b>	RIFAXIMIN 550 MG TABLETS: HE: TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# RIOCIQUAT

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: A) MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF LESS THAN OR EQUAL TO 15 MMHG, AND C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4: NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH, CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	<p>INITIAL: PAH: NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. CTEPH: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING NITRATES, NITRIC OXIDE DONORS, OR ANY PDE INHIBITORS, AND 2) NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL: PAH, CTEPH: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
<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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: PLAQUE PSORIASIS (PSO): PLAQUE PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE OR GENITAL AREA.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
<b>Other Criteria</b>	PSO: INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE, RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# RISDIPLAM

## Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	SMA: PRESCRIBED BY OR GIVEN IN CONSULTATION WITH A NEUROMUSCULAR SPECIALIST OR SPINAL MUSCULAR ATROPHY (SMA) SPECIALIST AT A SMA SPECIALTY CENTER.
Coverage Duration	SMA: INITIAL/RENEWAL: 12 MONTHS
Other Criteria	SPINAL MUSCULAR ATROPHY (SMA): INITIAL: DOCUMENTATION OF GENE MUTATION ANALYSIS INDICATING MUTATIONS OR DELETIONS OF BOTH ALLELES OF THE SURVIVAL MOTOR NEURON 1 (SMN1) GENE. FOR PRESYMPTOMATIC PATIENTS: DOCUMENTATION OF UP TO THREE COPIES OF SURVIVAL MOTOR NEURON 2 (SMN2) BASED ON NEWBORN SCREENING. FOR SYMPTOMATIC PATIENTS: 1) ONSET OF SMA SYMPTOMS OCCURRED BEFORE 20 YEARS OF AGE, 2) DOCUMENTATION OF BASELINE MOTOR FUNCTION ASSESSMENT BY A NEUROMUSCULAR SPECIALIST OR SMA SPECIALIST, 3) IF PREVIOUSLY RECEIVED GENE THERAPY, THE PATIENT HAD LESS THAN EXPECTED CLINICAL BENEFIT. RENEWAL: IMPROVED, MAINTAINED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN MOTOR FUNCTION ASSESSMENTS COMPARED TO BASELINE, OR OTHER MUSCLE FUNCTION.

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

# 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 IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, PV, WG, MPA: 12 MO. CLL: 6 MO.
Other Criteria	RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, RINVOQ, RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	



# RITUXIMAB AND HYALURONIDASE HUMAN-SQ

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## Products Affected

- RITUXAN HYCELA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PATIENT HAS RECEIVED OR WILL RECEIVE AT LEAST ONE FULL DOSE OF A RITUXIMAB PRODUCT BY INTRAVENOUS INFUSION PRIOR TO INITIATION OF RITUXIMAB AND HYALURONIDASE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	

# RITUXIMAB-ABBS

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## Products Affected

- TRUXIMA

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

# RITUXIMAB-ARRX

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## Products Affected

- RIABNI

<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 IN CONSULTATION WITH AN ONCOLOGIST.
<b>Coverage Duration</b>	NHL, WG, MPA: 12 MONTHS. CLL: 6 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>	

# 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 IN CONSULTATION WITH AN ONCOLOGIST.
<b>Coverage Duration</b>	NHL, WG, MPA: 12 MONTHS. CLL: 6 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>	METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG.
<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>	<p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	<p>MYELOFIBROSIS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. POLYCYTHEMIA VERA, GVHD: 12 MONTHS.</p>
<b>Other Criteria</b>	
<b>Indications</b>	<p>All FDA-approved Indications.</p>
<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>	

# 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. 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)
- COSENTYX SUBCUTANEOUS SYRINGE 75 MG/0.5 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR A DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS

PA Criteria	Criteria Details
<b>Other Criteria</b>	INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG). AS, NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG). RENEWAL: PSO, PSA, AS, NR-AXSPA: CONTINUES TO BENEFIT FROM THE MEDICATION.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# SELEXIPAG

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	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

# SELINEXOR

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## Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (20 MG X 2), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 40MG TWICE WEEK (80 MG/WEEK), 60 MG/WEEK (20 MG X 3), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (20 MG X 4), 80 MG/WEEK (40 MG X 2), 80MG TWICE WEEK (160 MG/WEEK)

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



# 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
- MAYZENT STARTER 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>	MULTIPLE SCLEROSIS: RENEWAL: 1) DEMONSTRATION OF CLINICAL BENEFIT COMPARED TO PRE-TREATMENT BASELINE AND 2) DOES NOT HAVE LYMPHOPENIA.
<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: FOR PATIENTS 18 YEARS OR OLDER: TRIAL OF OR CONTRAINDICATION TO THE FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, PITOLISANT OR SOLRIAMFETOL AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. FOR PATIENTS 7 TO 17 YEARS OF AGE: TRIAL OF OR CONTRAINDICATION TO ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. RENEWAL: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# SOFOSBUVIR/VELPATASVIR

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## Products Affected

- EPCLUSA

<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

# SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

## Products Affected

- VOSEVI

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. PATIENT IS NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS NOT RECOMMENDED BY THE MANUFACTURER: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, CYCLOSPORINE, PITAVASTATIN, PRAVASTATIN (DOSES ABOVE 40MG), ROSUVASTATIN, METHOTREXATE, MITOXANTRONE, IMATINIB, IRINOTECAN, LAPATINIB, SULFASALAZINE, TOPOTECAN, OR HIV REGIMEN THAT CONTAINS EFAVIRENZ, ATAZANAVIR, LOPINAVIR OR TIPRANA VIR/RITONAVIR.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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. 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 - NORDITROPIN

## Products Affected

- NORDITROPIN FLEXPPO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
<b>Required Medical Information</b>	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), TURNER SYNDROME (TS), NOONAN SYNDROME: HEIGHT AT LEAST 2 STANDARD DEVIATIONS (SD) BELOW THE MEAN HEIGHT FOR NORMAL CHILDREN OF THE SAME AGE AND GENDER. PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	INITIAL AND RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	INITIAL: ADULT GHD: GROWTH HORMONE DEFICIENCY ALONE OR ASSOCIATED WITH MULTIPLE HORMONE DEFICIENCIES (HYPOPITUITARISM), AS A RESULT OF PITUITARY DISEASES, HYPOTHALAMIC DISEASE, SURGERY, RADIATION THERAPY, TRAUMA, OR CONTINUATION OF THERAPY FROM CHILDHOOD ONSET GROWTH HORMONE DEFICIENCY. PEDIATRIC GHD, ISS, SGA, TS, NOONAN SYNDROME: OPEN EPIPHYSES. RENEWAL: PEDIATRIC GHD, ISS, SGA, TS, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES. PWS: IMPROVEMENT IN BODY COMPOSITION.
<b>Indications</b>	All FDA-approved Indications.

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

# SOMATROPIN - SEROSTIM

## Products Affected

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

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

# 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>	SHORT BOWEL: PRESCRIBED BY OR 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>	

# 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>	

# SOTORASIB

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## Products Affected

- LUMAKRAS

<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

# STIRIPENTOL

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## Products Affected

- DIACOMIT ORAL CAPSULE 250 MG, 500 MG
- DIACOMIT ORAL POWDER IN PACKET 250 MG, 500 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>	DRAVET SYNDROME: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	RENEWAL: DRAVET SYNDROME: CURRENTLY TREATED WITH CLOBAZAM.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	



# SUNITINIB MALATE

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## Products Affected

- *sunitinib*

<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 99MTCPPYP/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
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	1) IMLYGIC TO BE INJECTED INTO CUTANEOUS, SUBCUTANEOUS, AND/OR NODAL LESIONS THAT ARE VISIBLE, PALPABLE, OR DETECTABLE BY ULTRASOUND GUIDANCE, 2) NOT CURRENTLY RECEIVING IMMUNOSUPPRESSIVE THERAPY, 3) NO HISTORY OF PRIMARY OR ACQUIRED IMMUNODEFICIENT STATES, LEUKEMIA, LYMPHOMA, OR AIDS, AND 4) NO CONCURRENT USE WITH PEMBROLIZUMAB, NIVOLUMAB, IPILIMUMAB, DABRAFENIB, TRAMETINIB, VEMURAFENIB, INTERLEUKIN-2, INTERFERON, DACARBAZINE, TEMOZOLOMIDE, PACLITAXEL, CARBOPLATIN, IMATINIB, MELPHALAN, IMIQUIMOD, OR RADIATION THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	

# TASIMELTEON

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## Products Affected

- HETLIOZ
- HETLIOZ LQ

<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>	NON-24 HOUR SLEEP-WAKE DISORDER: 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>	

# TEPOTINIB

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## Products Affected

- TEPMETKO

<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>	

# TESAMORELIN

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## Products Affected

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

PA Criteria	Criteria Details
<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>	

# TIVOZANIB

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## Products Affected

- FOTIVDA

<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>	

# TOFACITINIB

## Products Affected

- XELJANZ
- XELJANZ XR

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

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

# TOLVAPTAN

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## Products Affected

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLETS, SEQUENTIAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	RENEWAL: PHYSICIAN ATTESTATION THAT PATIENT HAS NOT PROGRESSED TO ESRD/DIALYSIS OR TRANSPLANT.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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

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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>	
<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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	

# 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>	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA.
<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>	ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER: TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING PREFERRED AGENTS: HERZUMA, OGIVRI, ONTRUZANT, TRAZIMERA. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
<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
Exclusion Criteria	
Required Medical Information	<p>INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: A) MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF LESS THAN OR EQUAL TO 15 MMHG, AND C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) III-IV SYMPTOMS. PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: 1) MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 30 MMHG, 2) PULMONARY VASCULAR RESISTANCE (PVR) OF AT LEAST 4 WOOD UNITS, AND 3) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF LESS THAN OR EQUAL TO 12 MMHG IF PVR IS 4 WU TO LESS THAN 6.25 WU, OR PCWP OF LESS THAN OR EQUAL TO 15 MMHG IF PVR IS AT LEAST 6.25 WU.</p>
Age Restrictions	
Prescriber Restrictions	PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	PAH: INITIAL AND RENEWAL: 12 MONTHS. PH-ILD: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>INITIAL: PAH: WHO FC III SYMPTOMS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIAL RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR 3) FORMULARY VERSION OF AN ORAL CGMP INHIBITOR. WHO FC III SYMPTOMS AND EVIDENCE OF RAPID PROGRESSION OR POOR PROGNOSIS, WHO FC IV SYMPTOMS: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF AN IV/SQ PROSTACYCLIN. RENEWAL: PAH: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST OR REMAINED STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FC HAS IMPROVED OR REMAINED STABLE. PH-ILD: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST OR A STABLE 6-MINUTE WALK DISTANCE TEST. 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.</p>
<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>	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: MEAN PULMONARY ARTERY PRESSURE (PAP) OF AT LEAST 25 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF LESS THAN OR EQUAL TO 15 MMHG, AND C) PULMONARY VASCULAR RESISTANCE (PVR) GREATER THAN 3 WOOD UNITS, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PAH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
<b>Coverage Duration</b>	PAH: INITIAL AND RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	INITIAL: PAH: CONTINUATION FROM HOSPITAL DISCHARGE FOR WHO FC II-IV: NO STEP. NEW STARTS FOR WHO FC III-IV: NO STEP. NEW STARTS FOR WHO FC II: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS FROM DIFFERENT DRUG CLASSES: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIAL RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR 3) FORMULARY VERSION OF AN ORAL CGMP INHIBITOR. RENEWAL: PAH: IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST OR REMAINED STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FC HAS IMPROVED OR REMAINED STABLE. 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

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## Products Affected

- *clovique*
- *trientine*

<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

# 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>	

# UBROGEPANT

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## Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: TRIAL OF OR CONTRAINDICATION TO ONE FORMULARY TRIPTAN. RENEWAL: THE PATIENT HAS EXPERIENCED AN IMPROVEMENT FROM BASELINE IN A VALIDATED ACUTE TREATMENT PATIENT-REPORTED OUTCOME QUESTIONNAIRE OR THE PATIENT HAS EXPERIENCED CLINICAL IMPROVEMENT AS DEFINED BY ONE OF THE FOLLOWING: 1) ABILITY TO FUNCTION NORMALLY WITHIN 2 HOURS OF DOSE, 2) HEADACHE PAIN DISAPPEARS WITHIN 2 HOURS OF DOSE, 3) THERAPY WORKS CONSISTENTLY IN MAJORITY OF MIGRAINE ATTACKS.
Indications	All FDA-approved Indications.
Off Label Uses	



# UMBRALISIB

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## Products Affected

- UKONIQ

<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 (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF A PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED, RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	

# URIDINE TRIACETATE

## 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

## Products Affected

- STELARA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS INVOLVING GREATER THAN OR EQUAL TO 5 PERCENT OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
<b>Coverage Duration</b>	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
<b>Other Criteria</b>	INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

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

# 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), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
<b>Coverage Duration</b>	2 MONTHS
<b>Other Criteria</b>	CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
<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

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## 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

## Products Affected

- MEPSEVII

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

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

# VIGABATRIN

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## Products Affected

- *vigabatrin*
- *vigadrone*

<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>	REFRACTORY COMPLEX PARTIAL SEIZURES (CPS), INFANTILE SPASMS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
<b>Coverage Duration</b>	12 MONTHS
<b>Other Criteria</b>	CPS: PATIENT HAS RESPONDED INADEQUATELY TO AT LEAST 2 ANTIEPILEPTIC AGENTS. CPS AND INFANTILE SPASMS: BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# 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>	

# VORICONAZOLE SUSPENSION

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## Products Affected

- *voriconazole oral suspension for reconstitution*

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

# 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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