

ABALOPARATIDE

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS

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

ABATACEPT IV

Products Affected

- ORENCIA (WITH MALTOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	RA, PJIA, PSA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. AGVHD: 12 MONTHS.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

ABATACEPT SQ

Products Affected

- ORENCIA
- ORENCIA CLICKJECT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ATNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. RENEWAL: RA, PJIA, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

ABEMACICLIB

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED OR METASTATIC BREAST CANCER: HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ABIRATERONE

Products Affected

- *abiraterone*

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

ABIRATERONE SUBMICRONIZED

Products Affected

- YONSA

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

ACALABRUTINIB

Products Affected

- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)

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

ADALIMUMAB

Products Affected

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

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

PA Criteria	Criteria Details
Other Criteria	<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, CALCIPOTRIEN E, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. UVEITIS: NO ISOLATED ANTERIOR UVEITIS. RENEWAL: RA, PJIA, PSA, AS, PSO, HIDRADENITIS SUPPURATIVA, UVEITIS: CONTINUES TO BENEFIT FROM THE MEDICATION.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

AFATINIB

Products Affected

- GILOTRIF

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

AGALSIDASE BETA

Products Affected

- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FABRY DISEASE: INITIAL: PATIENT IS SYMPTOMATIC OR HAS EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS.
Age Restrictions	
Prescriber Restrictions	FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	FABRY DISEASE: INITIAL: NOT CONCURRENTLY USING AN ALPHA-GAL A PHARMACOLOGICAL CHAPERONE (I.E., GALAFOLD (MIGALASTAT)). RENEWAL: 1) DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NOT CONCURRENTLY USING AN ALPHA-GAL A PHARMACOLOGICAL CHAPERONE (I.E., GALAFOLD (MIGALASTAT)).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ALECTINIB

Products Affected

- ALECENSA

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

ALPELISIB

Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

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

AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: PATIENT DOES NOT HAVE IDIOPATHIC PULMONARY FIBROSIS. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE, OR 2) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

AMIVANTAMAB-VMJW

Products Affected

- RYBREVANT

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

ANAKINRA

Products Affected

- KINERET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS. ALL OTHERS: 12 MONTHS.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

APALUTAMIDE

Products Affected

- ERLEADA

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

APOMORPHINE

Products Affected

- *apomorphine*

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

APOMORPHINE - SL

Products Affected

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

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

APREMILAST

Products Affected

- OTEZLA
- OTEZLA STARTER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: MILD PLAQUE PSORIASIS (PSO): ONE OF THE FOLLOWING: 1) PSORIASIS COVERING 2 PERCENT OF BODY SURFACE AREA (BSA), 2) STATIC PHYSICIAN GLOBAL ASSESSMENT (SPGA) SCORE OF 2, OR 3) PSORIASIS AREA AND SEVERITY INDEX (PASI) SCORE OF 2 TO 9. MODERATE TO SEVERE PSO: 1) PSORIASIS COVERING 3 PERCENT OR MORE OF BSA, OR 2) PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA.
Age Restrictions	
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. BEHCETS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. MILD PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL SYSTEMIC AGENT (E.G., METHOTREXATE, ACITRETIN, CYCLOSPORINE) AND ONE CONVENTIONAL TOPICAL AGENT (E.G., PUVA, UVB, TOPICAL CORTICOSTEROIDS). MODERATE TO SEVERE PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. BEHCETS DISEASE: 1) PATIENT HAS ORAL ULCERS OR A HISTORY OF RECURRENT ORAL ULCERS BASED ON CLINICAL SYMPTOMS, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE OR MORE CONSERVATIVE TREATMENTS (E.G., COLCHICINE, TOPICAL CORTICOSTEROID, ORAL CORTICOSTEROID). RENEWAL: PSA, PSO, BEHCETS DISEASE: CONTINUES TO BENEFIT FROM THE MEDICATION.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ASCIMINIB

Products Affected

- SCEMBLIX

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

ASFOTASE

Products Affected

- STRENSIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	HYPOPHOSPHATASIA (HPP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, OR METABOLIC SPECIALIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: PERINATAL/INFANTILE-ONSET HPP: 1) 6 MONTHS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP) (ALPL) GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALKALINE PHOSPHATASE (ALP) LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PYRIDOXAL-5'-PHOSPHATE (PLP) LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PHOSPHOETHANOLAMINE (PEA) LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC CHEST DEFORMITY, (II) CRANIOSYNOSTOSIS, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV) HISTORY OF VITAMIN B6 DEPENDENT SEIZURES, (V) NEPHROCALCINOSIS OR HISTORY OF ELEVATED SERUM CALCIUM, (VI) HISTORY OR PRESENCE OF NON-TRAUMATIC POSTNATAL FRACTURE AND DELAYED FRACTURE HEALING. JUVENILE-ONSET HPP: 1) 18 YEARS OF AGE OR YOUNGER AT ONSET OF HPP, AND 2) POSITIVE FOR A TNSALP ALPL GENE MUTATION AS CONFIRMED BY GENETIC TESTING OR TWO OF THE FOLLOWING: (A) SERUM ALP LEVEL BELOW THAT OF NORMAL RANGE FOR PATIENT AGE, (B) ELEVATED SERUM PLP LEVELS AND NO VITAMIN B6 SUPPLEMENTATION IN THE PREVIOUS WEEK, (C) URINE PEA LEVEL ABOVE THAT OF NORMAL RANGE FOR PATIENT AGE, (D) RADIOGRAPHIC EVIDENCE OF HPP, (E) AT LEAST TWO OF THE FOLLOWING: (I) RACHITIC DEFORMITIES, (II) PREMATURE LOSS OF PRIMARY TEETH PRIOR TO 5 YEARS OF AGE, (III) DELAY IN SKELETAL GROWTH RESULTING IN DELAY OF MOTOR DEVELOPMENT, (IV)</p>

PA Criteria	Criteria Details
	<p>HISTORY OR PRESENCE OF NON-TRAUMATIC FRACTURES OR DELAYED FRACTURE HEALING. ALL INDICATIONS: 1) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE, 2) CALCIUM OR PHOSPHATE LEVELS ARE NOT BELOW THE NORMAL RANGE, 3) NOT HAVE A TREATABLE FORM OF RICKETS. RENEWAL: ALL INDICATIONS: 1) IMPROVEMENT IN THE SKELETAL CHARACTERISTICS OF HPP, AND 2) NOT CURRENTLY RECEIVING TREATMENT WITH A BISPHOSPHONATE.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ATEZOLIZUMAB

Products Affected

- TECENTRIQ

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

ATOGEPANT

Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

AVAPRITINIB

Products Affected

- AYVAKIT

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

AVATROMBOPAG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: CHRONIC LIVER DISEASE (CLD): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, GASTROENTEROLOGIST, HEPATOLOGIST, IMMUNOLOGIST, ENDOCRINOLOGIST, OR A SURGEON. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	CLD: 1 MONTH. CHRONIC ITP: INITIAL: 2 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: CLD: 1) PLANNED PROCEDURE 10 TO 13 DAYS AFTER INITIATION OF DOPTELET, AND 2) NOT RECEIVING OTHER THROMBOPOIETIN RECEPTOR AGONISTS (E.G., ROMIPLOSTIM, ELTROMBOPAG, ETC.). CHRONIC ITP: TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS OR IMMUNOGLOBULINS OR INSUFFICIENT RESPONSE TO SPLENECTOMY. RENEWAL: CHRONIC ITP: PATIENT HAD A CLINICAL RESPONSE.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

AXITINIB

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

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

AZACITIDINE

Products Affected

- ONUREG

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

AZTREONAM

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	7 YEARS OF AGE OR OLDER
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

BARICITINIB

Products Affected

- OLUMIANT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	RA: INITIAL: TRIAL OF OR CONTRAINDICATION TO ANY TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

BECAPLERMIN

Products Affected

- REGRANEX

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

BEDAQUILINE

Products Affected

- SIRTURO

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

BELIMUMAB

Products Affected

- BENLYSTA INTRAVENOUS
- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. LUPUS NEPHRITIS (LN): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR NEPHROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: SLE: CURRENTLY TAKING CORTICOSTEROIDS, ANTIMALARIALS, NSAIDS, OR IMMUNOSUPPRESSIVE AGENTS. RENEWAL: SLE: PATIENT HAD CLINICAL IMPROVEMENT. LN: IMPROVEMENT IN RENAL RESPONSE FROM BASELINE LABORATORY VALUES (I.E., EGFR OR PROTEINURIA) AND/OR CLINICAL PARAMETERS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

BELUMOSUDIL

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

BELZUTIFAN

Products Affected

- WELIREG

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

BENDAMUSTINE

Products Affected

- BENDEKA

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

BENRALIZUMAB

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ASTHMA: INITIAL: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	
Prescriber Restrictions	ASTHMA: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	INITIAL: 4 MONTHS, RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE, OR MAXIMALLY-TOLERATED DOSE OF AN INHALED CORTICOSTEROID (ICS) AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) PATIENT EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) PATIENT HAS POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. RENEWAL: 1) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE, OR (D) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

BETAINE

Products Affected

- *betaine*

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

BEVACIZUMAB-AWWB

Products Affected

- MVASI

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

BEVACIZUMAB-BVZR

Products Affected

- ZIRABEV

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

BEXAROTENE

Products Affected

- *bexarotene*

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

BINIMETINIB

Products Affected

- MEKTOVI

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

BORTEZOMIB

Products Affected

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

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

BOSENTAN

Products Affected

- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: INITIAL: 1) DOES NOT HAVE ELEVATED LIVER ENZYMES (ALT, AST) MORE THAN 3 TIMES UPPER LIMIT OF NORMAL (ULN) OR INCREASE IN BILIRUBIN BY 2 OR MORE TIMES ULN, AND 2) NOT CONCURRENTLY TAKING CYCLOSPORINE A OR GLYBURIDE. RENEWAL: 1) NOT CONCURRENTLY TAKING CYCLOSPORINE A OR GLYBURIDE, 2) AGES 3 TO 17 YEARS OF AGE: A) DEMONSTRATED IMPROVEMENT IN PVR, OR B) REMAINED STABLE OR SHOWN IMPROVEMENT IN EXERCISE ABILITY, 3) AGES 18 YEARS OR OLDER: A) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE, OR B) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS.

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

BOSUTINIB

Products Affected

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

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

BRIGATINIB

Products Affected

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

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

C1 ESTERASE INHIBITOR-CINRYZE

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
Age Restrictions	
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

C1 ESTERASE INHIBITOR-HAEGARDA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
Age Restrictions	
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST, IMMUNOLOGIST, OR ALLERGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS.
Other Criteria	HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CABOZANTINIB

Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

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

CABOZANTINIB S-MALATE - CABOMETYX

Products Affected

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

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

CANAKINUMAB

Products Affected

- ILARIS (PF)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: 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.
Coverage Duration	INITIAL: AOSD, SJIA: 6 MONTHS, RENEWAL:12 MONTHS. ALL OTHER INDICATIONS: 12 MONTHS.
Other Criteria	INITIAL: AOSD, SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUGS). RENEWAL: AOSD, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CANNABIDIOL

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	DRAVET SYNDROME (DS), LENNOX-GASTAUT SYNDROME (LGS), TUBEROUS SCLEROSIS COMPLEX (TSC): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: LENNOX-GASTAUT SYNDROME (LGS): TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING ANTIEPILEPTIC MEDICATIONS: RUFINAMIDE, FELBAMATE, CLOBAZAM, TOPIRAMATE, LAMOTRIGINE, CLONAZEPAM. RENEWAL: DS, LGS, TSC: CONFIRMATION OF DIAGNOSIS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CAPLACIZUMAB YHDP

Products Affected

- CABLIVI INJECTION KIT

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

CAPMATINIB

Products Affected

- TABRECTA

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

CARGLUMIC ACID

Products Affected

- *carglumic acid*

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

CERITINIB

Products Affected

- ZYKADIA ORAL TABLET

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

CERTOLIZUMAB PEGOL

Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO HUMIRA AND STELARA. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: COSENTYX. PATIENTS WHO ARE PREGNANT, BREASTFEEDING, OR TRYING TO BECOME PREGNANT ARE EXCLUDED FROM STEP CRITERIA FOR ALL INDICATIONS. RENEWAL: RA, PSA, AS, PSO, NR-AXSPA: CONTINUES TO BENEFIT FROM THE MEDICATION.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CETUXIMAB

Products Affected

- ERBITUX

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

CLADRIBINE

Products Affected

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

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

CLOBAZAM-SYMPAZAN

Products Affected

- SYMPAZAN

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

COBIMETINIB

Products Affected

- COTELLIC

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

COLCHICINE

Products Affected

- *colchicine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	PROPHYLAXIS OF GOUT FLARES: 16 YEARS AND OLDER
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PROPHYLAXIS OF GOUT FLARES: TRIAL OF OR CONTRAINDICATION TO COLCHICINE CAPSULES (MITIGARE) IF AGE 18 YEARS OR OLDER.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CORTICOTROPIN

Products Affected

- ACTHAR
- CORTROPHIN GEL

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL: NOT APPROVED FOR DIAGNOSTIC PURPOSES.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MULTIPLE SCLEROSIS (MS): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST/IMMUNOLOGIST, OPHTHALMOLOGIST, PULMONOLOGIST OR NEPHROLOGIST.
Coverage Duration	INFANTILE SPASMS AND MS: 28 DAYS. OTHER FDA APPROVED INDICATIONS: INITIAL AND RENEWAL: 28 DAYS
Other Criteria	INITIAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS: TRIAL OF OR CONTRAINDICATION TO INTRAVENOUS (IV) CORTICOSTEROIDS. ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: TRIAL OF OR CONTRAINDICATION TO A STANDARD OF CARE THERAPY. RENEWAL: ALL FDA APPROVED INDICATIONS EXCEPT INFANTILE SPASMS AND MS: 1) DEMONSTRATED CLINICAL BENEFIT WHILE ON THERAPY AS INDICATED BY SYMPTOM RESOLUTION AND/OR NORMALIZATION OF LABORATORY TESTS, AND 2) CONTINUES TO POSSESS CONTRAINDICATION TO IV CORTICOSTEROIDS. PART B BEFORE PART D STEP THERAPY, APPLIES ONLY TO BENEFICIARIES IN AN MA-PD PLAN.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

CRIZANLIZUMAB-TMCA

Products Affected

- ADAKVEO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	SICKLE CELL DISEASE (SCD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME
Other Criteria	SCD: INITIAL: ADULTS (18 YEARS OR OLDER): ONE OF THE FOLLOWING: (1) AT LEAST 2 SICKLE CELL CRISES IN THE PAST YEAR, (2) SICKLE-CELL ASSOCIATED SYMPTOMS WHICH ARE INTERFERING WITH ACTIVITIES OF DAILY LIVING, OR (3) HISTORY OF OR HAS RECURRENT ACUTE CHEST SYNDROME (ACS). PATIENTS BETWEEN THE AGES OF 16 TO 17 YEARS, WILL BE APPROVED WITHOUT REQUIRING ADDITIONAL CRITERIA. RENEWAL FOR ALL PATIENTS: MAINTAINED OR EXPERIENCED A REDUCTION IN ACUTE COMPLICATIONS OF SICKLE CELL DISEASE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CRIZOTINIB

Products Affected

- XALKORI

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

CYSTEAMINE HYDROCHLORIDE

Products Affected

- CYSTADROPS
- CYSTARAN

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

DABRAFENIB

Products Affected

- TAFINLAR

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

DACOMITINIB

Products Affected

- VIZIMPRO

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

DALFAMPRIDINE

Products Affected

- *dalfampridine*

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

DARATUMUMAB

Products Affected

- DARZALEX

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

DARATUMUMAB-HYALURONIDASE-FIHJ

Products Affected

- DARZALEX FASPRO

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

DAROLUTAMIDE

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

DASATINIB

Products Affected

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

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

DECITABINE/CEDAZURIDINE

Products Affected

- INQOVI

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

DEFERASIROX

Products Affected

- *deferasirox*

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

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX (2 TIMES A DAY)
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	TRANSFUSIONAL IRON OVERLOAD: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES: 1) TRIAL OF, CONTRAINDICATION, INTOLERABLE TOXICITIES, OR CLINICALLY SIGNIFICANT ADVERSE EFFECTS TO ONE OF THE FOLLOWING: FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE, OR 2) CURRENT CHELATION THERAPY (I.E., FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE) IS INADEQUATE. TRANSFUSIONAL IRON OVERLOAD DUE TO SICKLE CELL DISEASE OR OTHER ANEMIAS: TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF DEFERASIROX OR DEFEROXAMINE. RENEWAL (ALL INDICATIONS): SERUM FERRITIN LEVELS CONSISTENTLY ABOVE 500MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS).
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

DEFEROXAMINE

Products Affected

- *deferoxamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	CHRONIC IRON OVERLOAD: 3 YEARS OR OLDER
Prescriber Restrictions	CHRONIC IRON OVERLOAD: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR HEMATOLOGIST/ONCOLOGIST
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	CHRONIC IRON OVERLOAD: INITIAL: SERUM FERRITIN LEVEL CONSISTENTLY ABOVE 1000MCG/L (AT LEAST TWO LAB VALUES IN THE PREVIOUS THREE MONTHS). RENEWAL: 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. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

DENOSUMAB-XGEVA

Products Affected

- XGEVA

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

DEUTETRABENAZINE

Products Affected

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

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

DICLOFENAC GEL

Products Affected

- *diclofenac sodium topical gel 3%*

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

DICLOFENAC TOPICAL SOLUTION

Products Affected

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

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

DIMETHYL FUMARATE

Products Affected

- *dimethyl fumarate oral capsule, delayed release(dr/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	
Part B Prerequisite	No

DIROXIMEL FUMARATE

Products Affected

- VUMERITY

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

DOSTARLIMAB-GXLY

Products Affected

- JEMPERLI

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

DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 MONTHS
Other Criteria	NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY: TRIAL OF OR CONTRAINDICATION TO ONE ANTIEMETIC THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D FOR THE INDICATION OF NAUSEA AND VOMITING ASSOCIATED WITH CANCER CHEMOTHERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

DROXIDOPA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH): INITIAL: 1) BASELINE BLOOD PRESSURE READINGS WHILE THE PATIENT IS SITTING AND ALSO WITHIN 3 MINUTES OF STANDING FROM A SUPINE POSITION. 2) A DECREASE OF AT LEAST 20 MMHG IN SYSTOLIC BLOOD PRESSURE OR 10 MMHG DIASTOLIC BLOOD PRESSURE WITHIN THREE MINUTES AFTER STANDING FROM A SITTING POSITION.
Age Restrictions	
Prescriber Restrictions	NOH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR CARDIOLOGIST.
Coverage Duration	INITIAL: 3 MONTHS RENEWAL: 12 MONTHS
Other Criteria	NOH: RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

DUPILUMAB

Products Affected

- DUPIXENT PEN
- DUPIXENT SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

DUVELISIB

Products Affected

- COPIKTRA

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

EDARAVONE

Products Affected

- RADICAVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR ALS SPECIALIST AT AN ALS SPECIALTY CENTER OR CARE CLINIC.
Coverage Duration	ALS: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	ALS: INITIAL: 1) DURATION OF DISEASE (FROM ONSET OF SYMPTOMS) IS LESS THAN OR EQUAL TO 2 YEARS, 2) NORMAL RESPIRATORY FUNCTION, 3) HAS MILD TO MODERATE ALS WITH A SCORE OF 2 OR HIGHER IN ALL OF THE FOLLOWING 12 ITEMS OF THE AMYOTROPHIC LATERAL SCLEROSIS FUNCTIONAL RATING SCALE REVISED (ALSFRS-R): SPEECH, SALIVATION, SWALLOWING, HANDWRITING, CUTTING FOOD, DRESSING AND HYGIENE, TURNING IN BED, WALKING, CLIMBING STAIRS, DYSPNEA, ORTHOPNEA, RESPIRATORY INSUFFICIENCY, AND 4) TRIAL OF RILUZOLE TABLET OR CURRENTLY TAKING RILUZOLE TABLET. RENEWAL: 1) DOES NOT REQUIRE INVASIVE VENTILATION, AND 2) HAS IMPROVED BASELINE FUNCTIONAL ABILITY OR HAS MAINTAINED A SCORE OF 2 OR HIGHER IN ALL 12 ITEMS OF THE ALSFRS-R.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

ELAGOLIX SODIUM

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

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

PA Criteria	Criteria Details
Part B Prerequisite	No

ELAPEGADEMASE-LVLR

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	ADENOSINE DEAMINASE SEVERE COMBINED IMMUNE DEFICIENCY (ADA-SCID): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH IMMUNOLOGIST, HEMATOLOGIST/ONCOLOGIST, OR PHYSICIAN SPECIALIZING IN INHERITED METABOLIC DISORDERS
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ADA-SCID: INITIAL: 1) ADA-SCID AS MANIFESTED BY ONE OF THE FOLLOWING: (A) CONFIRMATORY GENETIC TEST OR (B) SUGGESTIVE LABORATORY FINDINGS (E.G., ELEVATED DEOXYADENOSINE NUCLEOTIDE [DAXP] LEVELS, LYMPHOPENIA) AND HALLMARK SIGNS/SYMPTOMS (E.G., RECURRENT INFECTIONS, FAILURE TO THRIVE, PERSISTENT DIARRHEA), AND 2) PATIENT ALSO MEETS ONE OF THE FOLLOWING: (A) HAS FAILED OR IS NOT A CANDIDATE FOR HEMATOPOIETIC CELL TRANSPLANTATION (HCT) OR (B) REVCOVI WILL BE USED AS BRIDGING THERAPY PRIOR TO PLANNED HCT OR GENE THERAPY. RENEWAL: 1) IMPROVEMENT OR MAINTENANCE OF IMMUNE FUNCTION FROM BASELINE, AND 2) HAS NOT RECEIVED SUCCESSFUL HCT OR GENE THERAPY.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

ELEXACAFITOR-TEZACAFITOR-IVACAFITOR

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CYSTIC FIBROSIS (CF); INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS.
Age Restrictions	
Prescriber Restrictions	CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME.
Other Criteria	CF: RENEWAL: 1) MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR 2) REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ELIGLUSTAT

Products Affected

- CERDELGA

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

ELOSULFASE ALFA

Products Affected

- VIMIZIM

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

ELTROMBOPAG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: ITP: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	ITP: INITIAL: 2 MO, RENEWAL: 12 MO. HEPATITIS C, SEVERE APLASTIC ANEMIA: 12 MO.
Other Criteria	INITIAL: PERSISTENT OR CHRONIC IMMUNE THROMBOCYTOPENIA PURPURA (ITP): TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. ALL INDICATIONS: APPROVAL FOR PROMACTA ORAL SUSPENSION PACKETS REQUIRES A TRIAL OF PROMACTA TABLETS OR PATIENT IS UNABLE TO TAKE TABLET FORMULATION. RENEWAL: ITP: PATIENT HAS SHOWN A CLINICAL RESPONSE.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

EMAPALUMAB-LZSG

Products Affected

- GAMIFANT

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

PA Criteria	Criteria Details
Other Criteria	HLH: INITIAL: 1) CONCURRENT THERAPY WITH DEXAMETHASONE, AND 2) ONE OF THE FOLLOWING: (A) HAS REFRACTORY, RECURRENT, OR PROGRESSIVE DISEASE, OR (B) HAD A TRIAL OF OR INTOLERANCE TO CONVENTIONAL HLH THERAPY (I.E., CHEMOTHERAPY, STEROIDS, IMMUNOTHERAPY). RENEWAL: 1) HAS NOT RECEIVED SUCCESSFUL HEMATOPOIETIC STEM CELL TRANSPLANTATION, AND 2) DEMONSTRATED IMPROVED IMMUNE SYSTEM RESPONSE FROM BASELINE (E.G., RESOLUTION OF FEVER, DECREASED SPLENOMEGALY, IMPROVEMENT IN CNS SYMPTOMS, IMPROVED CBC, INCREASED FIBRINOGEN LEVELS, REDUCED D-DIMER, REDUCED FERRITIN, REDUCED SOLUBLE CD25 LEVELS.)
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ENASIDENIB

Products Affected

- IDHIFA

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

ENCORAFENIB

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

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

ENTRECTINIB

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

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

ENZALUTAMIDE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	INITIAL: CASTRATION-RESISTANT PROSTATE CANCER (CRPC) THAT IS NOT METASTATIC: PATIENT HAS HIGH RISK PROSTATE CANCER (I.E. RAPIDLY INCREASING PROSTATE SPECIFIC ANTIGEN [PSA] LEVELS). CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. RENEWAL: DIAGNOSIS OF CRPC (INCLUDES NON-METASTATIC AND METASTATIC) OR MCSPC.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

EPOETIN ALFA-EPBX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: CHRONIC KIDNEY DISEASE (CKD), ANEMIA RELATED TO ZIDOVUDINE, OR CANCER CHEMOTHERAPY: HEMOGLOBIN LEVEL OF LESS THAN 10G/DL. ELECTIVE, NON-CARDIAC, NON-VASCULAR SURGERY: HEMOGLOBIN LEVEL LESS THAN 13G/DL. RENEWAL: CKD: 1) HEMOGLOBIN LEVEL IS LESS THAN 10G/DL, OR 2) HEMOGLOBIN LEVEL HAS REACHED 10G/DL AND DOSE REDUCTION/INTERRUPTION IS REQUIRED TO REDUCE THE NEED FOR BLOOD TRANSFUSIONS. ANEMIA RELATED TO ZIDOVUDINE: HEMOGLOBIN LEVEL BETWEEN 10G/DL AND 12G/DL. CANCER CHEMOTHERAPY: 1) HEMOGLOBIN LEVEL OF LESS THAN 10 G/DL, OR 2) THE HEMOGLOBIN LEVEL DOES NOT EXCEED A LEVEL NEEDED TO AVOID RBC TRANSFUSION.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	ANEMIA FROM CHEMO/CKD WITHOUT DIALYSIS/ZIDOVUDINE: INITIAL/RENEWAL: 12 MONTHS. SURGERY: 1 MONTH.
Other Criteria	RENEWAL: CKD: NOT RECEIVING DIALYSIS TREATMENT. THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

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

EPOPROSTENOL IV

Products Affected

- *epoprostenol (glycine)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: (1) DOCUMENTED CONFIRMATORY PAH DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND (2) NYHA-WHO FUNCTIONAL CLASS III-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS
Other Criteria	PAH: 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 AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ERDAFITINIB

Products Affected

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

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

ERLOTINIB

Products Affected

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

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

ESKETAMINE

Products Affected

- SPRAVATO

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

ETANERCEPT

Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE OR GENITAL AREA.
Age Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS), PSORIATIC ARTHRITIS (PSA): 18 YEARS OR OLDER.
Prescriber Restrictions	INITIAL: RA, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), AS: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. PSA: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE: IS REQUIRED. PJIA, PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD. AS: TRIAL OF OR CONTRAINDICATION TO AN NSAID. PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. RENEWAL: RA, PJIA, PSA, AS, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ETEPLIRSEN

Products Affected

- EXONDYS-51

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	DUCHENNE MUSCULAR DYSTROPHY (DMD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	DMD: INITIAL: PATIENT IS AMBULATORY AND 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 (I.E., PULMONARY OR CARDIAC FUNCTION). THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic) oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus (antineoplastic) oral tablet for suspension*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED RENAL CELL CARCINOMA (RCC): TRIAL OF OR CONTRAINDICATION TO A FORMULARY VERSION OF SUNITINIB OR SORAFENIB.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FEDRATINIB

Products Affected

- INREBIC

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

FENFLURAMINE

Products Affected

- FINTEPLA

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

FENTANYL CITRATE

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

FILGRASTIM-AAFI

Products Affected

- NIVESTYM

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

FILGRASTIM-AYOW

Products Affected

- RELEUKO

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

FILGRASTIM-SNDZ

Products Affected

- ZARXIO

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

FINASTERIDE/TADALAFIL

Products Affected

- ENTADFI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	BENIGN PROSTATIC HYPERPLASIA (BPH): 18 YEARS OF AGE OR OLDER
Prescriber Restrictions	
Coverage Duration	26 WEEKS
Other Criteria	BPH: 1) TRIAL OF OR CONTRAINDICATION TO ONE 5-ALPHA-REDUCTASE INHIBITOR, AND 2) TRIAL OF OR CONTRAINDICATION TO TADALAFIL 2.5MG OR TADALAFIL 5MG.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FINERENONE

Products Affected

- KERENDIA

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

FINGOLIMOD

Products Affected

- GILENYA

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

FINGOLIMOD LAURYL SULFATE

Products Affected

- TASCENSO ODT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	MULTIPLE SCLEROSIS (MS): (1) UNABLE TO SWALLOW FINGOLIMOD CAPSULES, AND (2) TRIAL OF OR CONTRAINDICATION TO FINGOLIMOD 0.25MG CAPSULES.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FOSTAMATINIB

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	CHRONIC IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: 3 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	ITP: RENEWAL: PATIENT HAS SHOWN A CLINICAL RESPONSE.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FREMANEZUMAB-VFRM

Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

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

GALCANEZUMAB-GNLM

Products Affected

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

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

GANAXOLONE

Products Affected

- ZTALMY

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

GEFITINIB

Products Affected

- IRESSA

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

GILTERITINIB

Products Affected

- XOSPATA

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

GIVOSIRAN

Products Affected

- GIVLAARI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: GENETIC CONFIRMATION OF MUTATION OR ELEVATED URINARY OR PLASMA PBG (PORPHOBILINOGEN) OR ALA (AMINOLEVULINIC ACID).
Age Restrictions	
Prescriber Restrictions	ACUTE HEPATIC PORPHYRIA (AHP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GENETICIST, HEPATOLOGIST, HEMATOLOGIST, GASTROENTEROLOGIST, NEUROLOGIST, DERMATOLOGIST, OR A HEALTHCARE PROVIDER EXPERIENCED IN MANAGING AHP.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS
Other Criteria	AHP: INITIAL: EXPERIENCED TWO OR MORE AHP ATTACKS IN THE PAST 12 MONTHS. RENEWAL: 1) ACHIEVED OR MAINTAINED CLINICAL BENEFIT COMPARED TO BASELINE, AND 2) HAS NOT RECEIVED A LIVER TRANSPLANT. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

GLASDEGIB

Products Affected

- DAURISMO ORAL TABLET 100 MG,
25 MG

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

GLATIRAMER

Products Affected

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

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

GLECAPREVIR/PIBRENTASVIR

Products Affected

- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS
Age Restrictions	
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.

PA Criteria	Criteria Details
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) TRIAL OF A PREFERRED FORMULARY ALTERNATIVE INCLUDING HARVONI OR EPCLUSA WHEN THESE AGENTS ARE CONSIDERED ACCEPTABLE FOR TREATMENT OF THE SPECIFIC GENOTYPE PER AASLD/IDSA GUIDANCE, 3) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: CARBAMAZEPINE, RIFAMPIN, ETHINYL ESTRADIOL-CONTAINING MEDICATION, ATAZANAVIR, DARUNAVIR, LOPINAVIR, RITONAVIR, EFAVIRENZ, ATORVASTATIN, LOVASTATIN, SIMVASTATIN, ROSUVASTATIN AT DOSES GREATER THAN 10MG, CYCLOSPORINE AT DOSES GREATER THAN 100MG PER DAY, EPCLUSA, HARVONI, VOSEVI, OR ZEPATIER, 4) PATIENT MUST NOT HAVE PRIOR FAILURE OF A DAA REGIMEN WITH NS5A INHIBITOR AND HCV PROTEASE INHIBITOR, AND 5) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD PUGH B OR C).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

GLYCEROL PHENYL BUTYRATE

Products Affected

- RAVICTI

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

GOSERELIN

Products Affected

- ZOLADEX

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

HIGH CONCENTRATION ORAL OPIOID SOLUTIONS

Products Affected

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

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

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - CLEMASTINE

Products Affected

- *clemastine oral tablet 2.68 mg*

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

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - PROMETHAZINE

Products Affected

- *promethazine injection solution*
- *promethazine oral*
- *promethazine rectal*
- *promethegan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PRURITUS/URTICARIA/SEASONAL/PERENNIAL ALLERGY: 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.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

HIGH RISK DRUGS IN THE ELDERLY - ANTICHOLINERGICS - SCOPOLAMINE

Products Affected

- *scopolamine base*

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

HIGH RISK DRUGS IN THE ELDERLY - BARBITURATE COMBINATIONS

Products Affected

- *ascomp with codeine*
- *butalbital-acetaminop-caff-cod*
- *butalbital-acetaminophen oral tablet 50-325 mg*
- *butalbital-acetaminophen-caff oral capsule 50-325-40 mg*
- *butalbital-acetaminophen-caff oral tablet*
- *butalbital-aspirin-caffeine*
- *codeine-butalbital-asa-caff*
- *tencon*
- *zebutal*

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

HIGH RISK DRUGS IN THE ELDERLY - DIPYRIDAMOLE

Products Affected

- *dipyridamole oral*

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

HIGH RISK DRUGS IN THE ELDERLY - DISOPYRAMIDE

Products Affected

- *disopyramide phosphate oral capsule*

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

HIGH RISK DRUGS IN THE ELDERLY - 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
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	VULVAR/VAGINAL ATROPHY, OSTEOPOROSIS AND VASOMOTOR SYMPTOMS OF MENOPAUSE: PRESCRIBER ACKNOWLEDGEMENT/AWARENESS THAT THE DRUG IS CONSIDERED HIGH RISK FOR PATIENTS 65 YEARS AND OLDER. 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.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

HIGH RISK DRUGS IN THE ELDERLY - ENDOCRINE - SULFONYLUREAS

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	
Part B Prerequisite	No

HIGH RISK DRUGS IN THE ELDERLY - KETOROLAC

Products Affected

- *ketorolac injection cartridge 15 mg/ml* *mg/ml*
- *ketorolac injection solution 15 mg/ml, 30 mg/ml (1 ml)* • *ketorolac intramuscular solution*
- *ketorolac injection syringe 15 mg/ml, 30 mg/ml* • *ketorolac intramuscular syringe*
- *ketorolac oral*

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

HIGH RISK DRUGS IN THE ELDERLY - 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	
Part B Prerequisite	No

HIGH RISK DRUGS IN THE ELDERLY

ANTICHOLINERGICS -

CYPROHEPTADINE_CARBINOXAMINE

Products Affected

- *carbinoxamine maleate oral liquid*
- *carbinoxamine maleate oral tablet 4 mg*
- *cyproheptadine*

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

HIGH RISK DRUGS IN THE ELDERLY- 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

HIGH RISK DRUGS IN THE ELDERLY- DIPHENOXYLATE-ATROPINE

Products Affected

- *diphenoxylate-atropine*

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

HIGH RISK DRUGS IN THE ELDERLY- INDOMETHACIN

Products Affected

- *indomethacin oral capsule 25 mg, 50 mg*
- *indomethacin oral capsule, extended release*

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

HIGH RISK DRUGS IN THE ELDERLY- MEGESTROL

Products Affected

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

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

HIGH RISK DRUGS IN THE ELDERLY- PAROXETINE

Products Affected

- *paroxetine hcl*

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

HIGH RISK MEDICATIONS IN THE ELDERLY- PHENOBARBITAL

Products Affected

- *phenobarbital*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	APPROPRIATE HIGH RISK MEDICATION USE: 65 YEARS OF AGE OR OLDER. PA NOT REQUIRED FOR AGE 0-64 YEARS.
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	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	
Part B Prerequisite	No

HISTRELIN-SUPPRELIN LA

Products Affected

- SUPPRELIN LA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PEDIATRIC ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR BREAST DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR GENITAL DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). RENEWAL: 1) TANNER SCALE STAGING AT INITIAL DIAGNOSIS OF CPP HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) PATIENT HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

HYDROXYUREA

Products Affected

- SIKLOS ORAL TABLET 100 MG

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

IBRUTINIB

Products Affected

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

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

IBUPROFEN-FAMOTIDINE

Products Affected

- *ibuprofen-famotidine*

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

ICATIBANT

Products Affected

- *icatibant*
- *sajazir*

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

IDELALISIB

Products Affected

- ZYDELIG

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

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

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

INFIGRATINIB

Products Affected

- TRUSELTIQ

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

INFLIXIMAB

Products Affected

- *infliximab*

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

INFLIXIMAB-ABDA

Products Affected

- RENFLEXIS

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

INFLIXIMAB-AXXQ

Products Affected

- AVSOLA

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

INFLIXIMAB-DYYB

Products Affected

- INFLECTRA

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL, XELJANZ. PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, STELARA, COSENTYX, ENBREL. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, ENBREL, XELJANZ. CD: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA AND STELARA. UC: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, STELARA, XELJANZ. RENEWAL: RA, AS, PSO, PSA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

INTERFERON ALFA-2B

Products Affected

- INTRON A INJECTION RECON SOLN

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

INTERFERON FOR MS-AVONEX

Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

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

INTERFERON FOR MS-BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

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

INTERFERON FOR MS-PLEGRIDY

Products Affected

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

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

INTERFERON GAMMA-1B

Products Affected

- ACTIMMUNE

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

IPILIMUMAB

Products Affected

- YERVOY

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

ITRACONAZOLE SOLUTION

Products Affected

- *itraconazole oral solution*

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

IVACAF TOR

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CYSTIC FIBROSIS (CF); INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS
Age Restrictions	
Prescriber Restrictions	CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT
Coverage Duration	INITIAL: 12 MONTHS. RENEWAL: LIFETIME
Other Criteria	CF: INITIAL: NOT HOMOZYGOUS FOR F508DEL MUTATION IN CFTR GENE. RENEWAL: 1) MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR 2) REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

IVOSIDENIB

Products Affected

- TIBSOVO

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

IXAZOMIB

Products Affected

- NINLARO

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

IXEKIZUMAB

Products Affected

- TALTZ AUTOINJECTOR
- TALTZ SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, FACE, OR GENITAL AREA. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS, WHERE AGES ALIGN: HUMIRA, COSENTYX, STELARA, ENBREL. PSA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL, XELJANZ. AS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: ENBREL, HUMIRA, COSENTYX, XELJANZ. NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: COSENTYX. RENEWAL: PSO, PSA, AS, NR-AXSPA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LANADELUMAB

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HEREDITARY ANGIOEDEMA (HAE): INITIAL: DIAGNOSIS CONFIRMED BY COMPLEMENT TESTING.
Age Restrictions	
Prescriber Restrictions	HAE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ALLERGIIST, IMMUNOLOGIST, OR HEMATOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	HAE: INITIAL: NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS. RENEWAL: 1) IMPROVEMENT COMPARED TO BASELINE IN HAE ATTACKS (I.E., REDUCTIONS IN ATTACK FREQUENCY OR ATTACK SEVERITY), AND 2) NOT ON CONCURRENT TREATMENT WITH ALTERNATIVE PROPHYLACTIC AGENT FOR HAE ATTACKS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LANREOTIDE

Products Affected

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

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

LAPATINIB

Products Affected

- *lapatinib*

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

LAROTRECTINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	APPROVAL FOR VITRAKVI ORAL SOLUTION: TRIAL OF VITRAKVI CAPSULES OR PATIENT IS UNABLE TO TAKE CAPSULE FORMULATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LEDIPASVIR-SOFOSBUVIR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

LENALIDOMIDE

Products Affected

- *lenalidomide*
- REVLIMID ORAL CAPSULE 2.5 MG, 20 MG

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

LENVATINIB

Products Affected

- LENVIMA

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

LETERMIVIR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 MONTHS
Other Criteria	HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT): THERAPY WILL BE INITIATED BETWEEN DAY 0 AND DAY 28 POST TRANSPLANTATION AND PATIENT IS NOT RECEIVING THE MEDICATION BEYOND 100 DAYS POST TRANSPLANTATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LEUPROLIDE

Products Affected

- *leuprolide subcutaneous kit*

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

LEUPROLIDE-ELIGARD

Products Affected

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

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

LEUPROLIDE-LUPRON DEPOT

Products Affected

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

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

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

LEUPROLIDE-LUPRON DEPOT-PED

Products Affected

- LUPRON DEPOT-PED (3 MONTH) INTRAMUSCULAR KIT 11.25 MG, 15
INTRAMUSCULAR SYRINGE KIT 30 MG
- LUPRON DEPOT-PED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PEDIATRIC ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR BREAST DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR GENITAL DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). RENEWAL: 1) TANNER SCALE STAGING AT INITIAL DIAGNOSIS OF CPP HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) PATIENT HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LEVODOPA

Products Affected

- INBRIJA INHALATION CAPSULE,
W/INHALATION DEVICE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	PARKINSONS DISEASE (PD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	PD: INITIAL: 1) NOT CURRENTLY TAKING MORE THAN 1600MG OF LEVODOPA PER DAY, AND 2) PHYSICIAN HAS OPTIMIZED DRUG THERAPY FOR PARKINSONS DISEASE. RENEWAL: IMPROVEMENT WITH MOTOR FLUCTUATIONS DURING OFF EPISODES WITH THE USE OF INBRIJA.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

L-GLUTAMINE

Products Affected

- ENDARI

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

LIDOCAINE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIDOCAINE PRILOCAINE

Products Affected

- *lidocaine-prilocaine topical cream*

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

LOMITAPIDE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST.
Coverage Duration	12 MONTHS

PA Criteria	Criteria Details
Other Criteria	<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>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LONCASTUXIMAB TESIRINE-LPYL

Products Affected

- ZYNLONTA

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

LORLATINIB

Products Affected

- LORBRENA ORAL TABLET 100 MG,
25 MG

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

LUMACAF TOR-IVACAF TOR

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET 100-125 MG, 150-188 MG
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: CYSTIC FIBROSIS (CF): CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CF.
Age Restrictions	
Prescriber Restrictions	CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CF EXPERT.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: LIFETIME.
Other Criteria	CF: RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LUMASIRAN

Products Affected

- OXLUMO

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

MACITENTAN

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) DOCUMENTED CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) OF 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	PAH: RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE, OR 2) A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

MARGETUXIMAB-CMKB

Products Affected

- MARGENZA

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

MEPOLIZUMAB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: ASTHMA: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	
Prescriber Restrictions	INITIAL: ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN PULMONARY OR ALLERGY MEDICINE. NASAL POLYPS: PRESCRIBED BY OR IN CONSULTATION WITH AN OTOLARYNGOLOGIST, ALLERGIST OR IMMUNOLOGIST.
Coverage Duration	INITIAL: ASTHMA: 4 MO. NASAL POLYPS: 6 MO. OTHERS: 12 MO. RENEWAL: NASAL POLYPS, ASTHMA: 12 MO.

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) PATIENT EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) PATIENT HAS POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, AND 3) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. NASAL POLYPS: PREVIOUS 90 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID. RENEWAL: ASTHMA: 1) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: (A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, (B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, (C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR D) INCREASE IN PERCENT PREDICTED FEV1 FROM</p>
	<p>PRETREATMENT BASELINE. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE.</p>
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

METHYLNALTREXONE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ADVANCED ILLNESS: OPIOID-INDUCED CONSTIPATION.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 MONTHS FOR PATIENTS RECEIVING PALLIATIVE CARE, 12 MONTHS FOR CHRONIC, NON-CANCER PAIN.
Other Criteria	ADVANCED ILLNESS: PATIENT IS RECEIVING PALLIATIVE CARE. CHRONIC NON-CANCER PAIN: PATIENT HAS BEEN TAKING OPIOIDS FOR AT LEAST 4 WEEKS AND HAD A PREVIOUS TRIAL OF OR CONTRAINDICATION TO NALOXEGOL (MOVANTIK) AND LUBIPROSTONE (AMITIZA).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

METHYLNALTREXONE ORAL

Products Affected

- RELISTOR ORAL

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

MIDOSTAURIN

Products Affected

- RYDAPT

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

MIFEPRISTONE

Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CUSHINGS SYNDROME (CS): INITIAL: DIAGNOSIS CONFIRMED BY ONE OF THE FOLLOWING: 1) 24-HR URINE FREE CORTISOL (2 OR MORE TESTS TO CONFIRM), 2) OVERNIGHT 1MG DEXAMETHASONE TEST, OR 3) LATE NIGHT SALIVARY CORTISOL (2 OR MORE TESTS TO CONFIRM).
Age Restrictions	
Prescriber Restrictions	CS: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS.
Other Criteria	CS: INITIAL: HYPERCORTISOLISM IS NOT A RESULT OF CHRONIC GLUCOCORTICOIDS. RENEWAL: 1) CONTINUES TO HAVE IMPROVEMENT OF GLUCOSE TOLERANCE OR STABLE GLUCOSE TOLERANCE (E.G., REDUCED A1C, IMPROVED FASTING GLUCOSE, ETC.), 2) CONTINUES TO HAVE TOLERABILITY TO KORLYM, AND 3) CONTINUES TO NOT BE A CANDIDATE FOR SURGICAL TREATMENT OR HAS FAILED SURGERY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

MIGALASTAT

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FABRY DISEASE: INITIAL: PATIENT IS SYMPTOMATIC OR HAS EVIDENCE OF INJURY FROM GL-3 TO THE KIDNEY, HEART, OR CENTRAL NERVOUS SYSTEM RECOGNIZED BY LABORATORY, HISTOLOGICAL, OR IMAGING FINDINGS.
Age Restrictions	
Prescriber Restrictions	FABRY DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A NEPHROLOGIST, CARDIOLOGIST, OR SPECIALIST IN GENETICS OR INHERITED METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MOS. RENEWAL: 12 MOS.
Other Criteria	FABRY DISEASE: INITIAL: NOT CONCURRENTLY USING ENZYME REPLACEMENT THERAPY (I.E. FABRAZYME), RENEWAL: 1) PATIENT HAS DEMONSTRATED IMPROVEMENT OR STABILIZATION, AND 2) NOT CONCURRENTLY USING ENZYME REPLACEMENT THERAPY (I.E. FABRAZYME).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

MIGLUSTAT

Products Affected

- *miglustat*

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

MILTEFOSINE

Products Affected

- IMPAVIDO

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

MOBOCERTINIB

Products Affected

- EXKIVITY

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

NAFARELIN

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

NARCOLEPSY AGENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NATALIZUMAB

Products Affected

- TYSABRI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: CROHNS DISEASE (CD): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	MULTIPLE SCLEROSIS (MS): 12 MOS. CD: INITIAL: 6 MOS, RENEWAL: 12 MOS.
Other Criteria	INITIAL: MS: TRIAL OF TWO AGENTS INDICATED FOR THE TREATMENT OF MS. CD: TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENTS: HUMIRA AND STELARA. RENEWAL: CD: ONE OF THE FOLLOWING: 1) RECEIVED AT LEAST 12 MONTHS OF THERAPY WITH TYSABRI AND HAS NOT REQUIRED MORE THAN 3 MONTHS OF CORTICOSTEROID USE WITHIN THE PAST 12 MONTHS TO CONTROL THEIR CROHNS DISEASE WHILE ON TYSABRI, OR 2) HAS ONLY RECEIVED 6 MONTHS OF THERAPY WITH TYSABRI AND HAS TAPERED OFF CORTICOSTEROIDS DURING THE FIRST 24 WEEKS OF TYSABRI THERAPY. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

NAXITAMAB-GQGK

Products Affected

- DANYELZA

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

NERATINIB MALEATE

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	EARLY-STAGE (STAGE I-III) BREAST CANCER: MEDICATION IS BEING REQUESTED WITHIN 2 YEARS OF COMPLETING THE LAST TRASTUZUMAB DOSE. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

NILOTINIB

Products Affected

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

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

NINTEDANIB

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>INITIAL: IDIOPATHIC PULMONARY FIBROSIS (IPF): 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) BASELINE FORCED VITAL CAPACITY (FVC) AT LEAST 50% OF PREDICTED VALUE. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 40% OF PREDICTED VALUE. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (PF-ILD): 1) AT LEAST 10% FIBROSIS ON A CHEST HRCT, AND 2) BASELINE FVC AT LEAST 45% OF PREDICTED VALUE.</p>
Age Restrictions	
Prescriber Restrictions	<p>INITIAL: IPF: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST. SSC-ILD, PF-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR RHEUMATOLOGIST.</p>
Coverage Duration	<p>INITIAL: SSC-ILD: 6 MOS. IPF, PF-ILD: 12 MOS. RENEWAL (ALL INDICATIONS): 12 MOS.</p>

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: IPF: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ESBRIET (PIRFENIDONE). SSC-ILD: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., HEART FAILURE/FLUID OVERLOAD, DRUG-INDUCED LUNG TOXICITY, RECURRENT ASPIRATION), AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: ACTEMRA SUBQ. PF-ILD: LUNG FUNCTION AND RESPIRATORY SYMPTOMS OR CHEST IMAGING HAVE WORSENEDED/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.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

NIRAPARIB

Products Affected

- ZEJULA

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

NITISINONE

Products Affected

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

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

NIVOLUMAB

Products Affected

- OPDIVO

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

NIVOLUMAB-RELATLIMAB-RMBW

Products Affected

- OPDUALAG

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

OBETICHOLIC ACID

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

OCRELIZUMAB

Products Affected

- OCREVUS

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

OFATUMUMAB-SQ

Products Affected

- KESIMPTA PEN

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

OLANZAPINE/SAMIDORPHAN

Products Affected

- LYBALVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	SCHIZOPHRENIA/BIPOLAR I: PRESCRIBED BY OR IN CONSULTATION WITH A PSYCHIATRIST
Coverage Duration	12 MONTHS
Other Criteria	SCHIZOPHRENIA: (1) PATIENT IS AT HIGH RISK OF WEIGHT GAIN AND (2) TRIAL OF OR CONTRAINDICATION TO LATUDA OR ONE OF THE FOLLOWING ORAL ANTIPSYCHOTICS: RISPERIDONE, CLOZAPINE TABLET, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE. BIPOLAR I: (1) PATIENT IS AT HIGH RISK OF WEIGHT GAIN AND (2) TRIAL OF OR CONTRAINDICATION TO ONE OF THE FOLLOWING ORAL ANTIPSYCHOTICS: RISPERIDONE, OLANZAPINE, IMMEDIATE RELEASE QUETIAPINE FUMARATE, ZIPRASIDONE, ARIPIPRAZOLE.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

OLAPARIB

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER: 1) MEDICATION WILL BE USED AS MONOTHERAPY, AND 2) PATIENT HAS COMPLETED TWO OR MORE LINES OF PLATINUM-BASED CHEMOTHERAPY. ADVANCED GERMLINE BRCA-MUTATED OVARIAN CANCER AFTER 3 OR MORE LINES OF CHEMOTHERAPY: MEDICATION WILL BE USED AS MONOTHERAPY. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: 1) PREVIOUSLY RECEIVED A BILATERAL ORCHIECTOMY, OR 2) CASTRATE LEVEL OF TESTOSTERONE (I.E., LESS THAN 50 NG/DL), OR 3) CONCURRENT USE WITH A GONADOTROPIN RELEASING HORMONE (GNRH) ANALOG. ALL OTHER FDA APPROVED INDICATIONS ARE COVERED WITHOUT ADDITIONAL CRITERIA, EXCEPT THOSE CRITERIA IN THE FDA APPROVED LABEL.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

OMACETAXINE

Products Affected

- SYNRIBO

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

OMALIZUMAB

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: ASTHMA: POSITIVE SKIN PRICK OR BLOOD TEST (E.G., ELISA, FEIA) TO A PERENNIAL AEROALLERGEN AND A BASELINE IGE SERUM LEVEL 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
Other Criteria	<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: 1) PREVIOUS 90 DAY TRIAL OF ONE TOPICAL NASAL CORTICOSTEROID, AND 2) TRIAL OF OR CONTRAINDICATION TO ONE PREFERRED AGENT: NUCALA, DUPIXENT. ASTHMA: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, 2) ONE OF THE FOLLOWING: (A) PATIENT EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) PATIENT HAS POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, 3) NOT CONCURRENTLY RECEIVING DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA. RENEWAL: CIU: DIAGNOSIS OF CIU. NASAL POLYPS: CLINICAL BENEFIT COMPARED TO BASELINE. ASTHMA: 1) NOT CONCURRENTLY RECEIVING DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: A) REDUCTION IN ASTHMA</p>
	<p>EXACERBATIONS FROM BASELINE, B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE.</p>
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

OPICAPONE

Products Affected

- ONGENTYS

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

OSIMERTINIB

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	EGFR EXON 19 DELETIONS OR EXON 21 L858R MUTATIONS NON-SMALL CELL LUNG CANCER (NSCLC) AND METASTATIC NSCLC WITH EGFR T790M MUTATION: NOT ON CONCURRENT THERAPY WITH AN EGFR TYROSINE KINASE-INHIBITOR.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PACRITINIB

Products Affected

- VONJO

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

PALBOCICLIB

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

PALIVIZUMAB

Products Affected

- SYNAGIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: GESTATIONAL AGE
Age Restrictions	INITIAL AND RENEWAL: LESS THAN 24 MONTHS OF AGE.
Prescriber Restrictions	
Coverage Duration	CRITERIA CONSISTENT WITH THE CDC RSV CENSUS REGIONAL TREND. SEE OTHER CRITERIA.
Other Criteria	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT RECOMMENDATIONS FROM THE AMERICAN ACADEMY OF PEDIATRICS FOR PALIVIZUMAB PROPHYLAXIS FOR RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTIONS AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION RSV CENSUS REGIONAL TREND. APPROVAL WILL BE FOR UP TO A MAXIMUM OF 5 MONTHS DEPENDENT UPON REMAINING LENGTH OF RESPIRATORY SYNCYTIAL VIRUS SEASON. RENEWAL: ADDITIONAL 1 MONTH OF TREATMENT FOR CARDIOPULMONARY BYPASS SURGERY DURING RSV PROPHYLAXIS SEASON.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PANOBINOSTAT

Products Affected

- FARYDAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	MULTIPLE MYELOMA: RENEWAL: TOLERATED THE FIRST 8 CYCLES OF THERAPY WITHOUT UNRESOLVED SEVERE OR MEDICALLY SIGNIFICANT TOXICITY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PARATHYROID HORMONE

Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM: 1) TRIAL OF OR CONTRAINDICATION TO CALCITRIOL, 2) HYPOPARATHYROIDISM IS NOT DUE TO A CALCIUM SENSING RECEPTOR (CSR) MUTATION, AND 3) HYPOPARATHYROIDISM IS NOT CONSIDERED ACUTE POST-SURGICAL HYPOPARATHYROIDISM.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PASIREOTIDE DIASPARTATE

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	CUSHINGS DISEASE (CD): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	CD: RENEWAL: 1) CONTINUED IMPROVEMENT OF CUSHINGS DISEASE, AND 2) MAINTAINED TOLERABILITY TO SIGNIFOR.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PAZOPANIB

Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED SOFT TISSUE SARCOMA (STS): NOT USED FOR ADIPOCYTIC STS OR GASTROINTESTINAL STROMAL TUMORS (GIST)
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER. RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

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

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION - IV

Products Affected

- *sildenafil (pulm.hypertension) intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	DOCUMENTED CONFIRMATORY PULMONARY ARTERIAL HYPERTENSION (PAH) DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION. PATIENT HAS NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL AND RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, RENEWAL: 1) NOT CONCURRENTLY OR INTERMITTENTLY TAKING ORAL ERECTILE DYSFUNCTION AGENTS (E.G. CIALIS, VIAGRA), ANY ORGANIC NITRATES IN ANY FORM, OR GUANYLATE CYCLASE STIMULATORS, AND 2) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS.

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

PEGFILGRASTIM

Products Affected

- NEULASTA

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

PEGFILGRASTIM - APGF

Products Affected

- NYVEPRIA

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

PEGFILGRASTIM - CBQV

Products Affected

- UDENYCA

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

PEGFILGRASTIM - JMDB

Products Affected

- FULPHILA

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

PEGFILGRASTIM-BMEZ

Products Affected

- ZIEXTENZO

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

PEGFILGRASTIM-NEULASTA ONPRO

Products Affected

- NEULASTA ONPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	NON MYELOID MALIGNANCY, ACUTE RADIATION EXPOSURE: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR ONCOLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PEGVALIASE-PQPZ

Products Affected

- PALYNZIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	PHENYLKETONURIA (PKU): INITIAL: NOT ON CONCURRENT TREATMENT WITH KUVAN. RENEWAL: 1) PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NOT ON CONCURRENT TREATMENT WITH KUVAN .
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PEGVISOMANT

Products Affected

- SOMAVERT

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

PEMBROLIZUMAB

Products Affected

- KEYTRUDA

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

PEMIGATINIB

Products Affected

- PEMAZYRE

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

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: WILSONS DISEASE: 1) KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE, AND 2) REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRE A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN). CYSTINURIA: REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRES A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN) AND A FORMULARY VERSION OF TIOPRONIN (THIOLA)/THIOLA EC. RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED, AND 3) REQUESTS FOR FORMULARY VERSION OF PENICILLAMINE CAPSULE REQUIRES A TRIAL OF OR CONTRAINDICATION TO PENICILLAMINE TABLET (DEPEN). RENEWAL: RA: 1) NO HISTORY OR OTHER EVIDENCE OF RENAL INSUFFICIENCY, 2) EXPERIENCED OR MAINTAINED IMPROVEMENT IN TENDER JOINT COUNT OR SWOLLEN JOINT COUNT COMPARED TO BASELINE. WILSONS DISEASE, CYSTINURIA: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PEXIDARTINIB

Products Affected

- TURALIO

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

PIMAVANSERIN

Products Affected

- NUPLAZID

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

PIRFENIDONE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	IDIOPATHIC PULMONARY FIBROSIS (IPF): INITIAL: 1) A USUAL INTERSTITIAL PNEUMONIA (UIP) PATTERN AS EVIDENCED BY HIGH-RESOLUTION COMPUTED TOMOGRAPHY (HRCT) ALONE OR VIA A COMBINATION OF SURGICAL LUNG BIOPSY AND HRCT, AND 2) PREDICTED FORCED VITAL CAPACITY (FVC) OF AT LEAST 50% AT BASELINE.
Age Restrictions	IPF: INITIAL: 18 YEARS OR OLDER.
Prescriber Restrictions	IPF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.
Other Criteria	IPF: INITIAL: 1) DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS, SYSTEMIC SCLEROSIS, RHEUMATOID ARTHRITIS, RADIATION, SARCOIDOSIS, BRONCHIOLITIS OBLITERANS ORGANIZING PNEUMONIA, HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION, VIRAL HEPATITIS, OR CANCER). RENEWAL: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

POMALIDOMIDE

Products Affected

- POMALYST

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

PONATINIB

Products Affected

- ICLUSIG

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

POSACONAZOLE

Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	OROPHARYNGEAL CANDIDIASIS (OPC): 3 MONTHS. PROPHYLAXIS: 6 MONTHS. TREATMENT: 12 WEEKS.
Other Criteria	POSACONAZOLE SUSPENSION ONLY: 1) OPC: TRIAL OF OR CONTRAINDICATION TO FLUCONAZOLE OR ITRACONAZOLE. 2) PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTION: INABILITY TO SWALLOW TABLETS. POSACONAZOLE TABLETS ONLY: TREATMENT OF INVASIVE ASPERGILLOSIS: NO EXTRA CRITERIA REQUIRED. CONTINUATION OF THERAPY AFTER HOSPITAL DISCHARGE REQUIRES NO EXTRA CRITERIA.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PRALSETINIB

Products Affected

- GAVRETO

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

PRAMLINTIDE

Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

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

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

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

QUININE

Products Affected

- *quinine sulfate*

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

RAMUCIRUMAB

Products Affected

- CYRAMZA

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

REGORAFENIB

Products Affected

- STIVARGA

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

RELUGOLIX

Products Affected

- ORGOVYX

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

RESLIZUMAB

Products Affected

- CINQAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ASTHMA: INITIAL: BLOOD EOSINOPHIL LEVEL GREATER THAN OR EQUAL TO 150 CELLS/MCL WITHIN THE PAST 12 MONTHS.
Age Restrictions	
Prescriber Restrictions	ASTHMA: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN ALLERGY OR PULMONARY MEDICINE.
Coverage Duration	ASTHMA: INITIAL 4 MONTHS. RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>ASTHMA: INITIAL: 1) CONCURRENT THERAPY WITH A MEDIUM, HIGH-DOSE OR MAXIMALLY TOLERATED DOSE OF AN INHALED CORTICOSTEROID AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 2) ONE OF THE FOLLOWING: (A) PATIENT EXPERIENCED AT LEAST ONE ASTHMA EXACERBATION REQUIRING SYSTEMIC CORTICOSTEROID BURST LASTING 3 OR MORE DAYS WITHIN THE PAST 12 MONTHS OR AT LEAST ONE SERIOUS EXACERBATION REQUIRING HOSPITALIZATION OR ER VISIT WITHIN THE PAST 12 MONTHS, OR (B) PATIENT HAS POOR SYMPTOM CONTROL DESPITE CURRENT THERAPY AS EVIDENCED BY AT LEAST THREE OF THE FOLLOWING WITHIN THE PAST 4 WEEKS: DAYTIME ASTHMA SYMPTOMS MORE THAN TWICE/WEEK, ANY NIGHT WAKING DUE TO ASTHMA, SABA RELIEVER FOR SYMPTOMS MORE THAN TWICE/WEEK, ANY ACTIVITY LIMITATION DUE TO ASTHMA, 3) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: FASENRA, NUCALA, DUPIXENT, AND 4) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA.</p> <p>RENEWAL: 1) NOT CONCURRENTLY RECEIVING XOLAIR, DUPIXENT OR OTHER ANTI-IL5 BIOLOGICS WHEN THESE ARE USED FOR THE TREATMENT OF ASTHMA, 2) CONTINUED USE OF ICS AND AT LEAST ONE OTHER MAINTENANCE MEDICATION, AND 3) CLINICAL RESPONSE AS EVIDENCED BY ONE OF THE FOLLOWING: A) REDUCTION IN ASTHMA EXACERBATIONS FROM BASELINE, B) DECREASED UTILIZATION OF RESCUE MEDICATIONS, C) REDUCTION IN SEVERITY OR FREQUENCY OF ASTHMA-RELATED SYMPTOMS, OR D) INCREASE IN PERCENT PREDICTED FEV1 FROM PRETREATMENT BASELINE. THIS DRUG ALSO REQUIRES</p>
	PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

RIBOCICLIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	ADVANCED OR METASTATIC BREAST CANCER: 1) REQUIRES A TRIAL OF OR CONTRAINDICATION TO VERZENIO OR IBRANCE WHERE INDICATIONS ALIGN AND 2) PATIENT HAS NOT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR CDK INHIBITOR THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RIFAXIMIN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	TRAVELERS DIARRHEA/HE: 12 MOS. IBS-D: 8 WKS.
Other Criteria	RIFAXIMIN 550 MG TABLETS: HE: TRIAL OF OR CONTRAINDICATION TO LACTULOSE OR CONCURRENT LACTULOSE THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RIMEGEPANT

Products Affected

- NURTEC ODT

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

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

RIOCIQUAT

Products Affected

- ADEMPAS

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) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4: NYHA-WHO FUNCTIONAL CLASS II-IV SYMPTOMS.</p>
Age Restrictions	
Prescriber Restrictions	<p>INITIAL: PAH, CTEPH: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.</p>
Coverage Duration	<p>INITIAL AND RENEWAL: 12 MONTHS.</p>

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: PAH: NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS. CTEPH: 1) NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, OR ANY PDE INHIBITORS, AND 2) NOT A CANDIDATE FOR SURGERY OR HAS INOPERABLE CTEPH OR HAS PERSISTENT OR RECURRENT DISEASE AFTER SURGICAL TREATMENT. RENEWAL: PAH, CTEPH: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE OR A STABLE 6-MINUTE WALK DISTANCE WITH A STABLE/IMPROVED WHO FUNCTIONAL CLASS, AND 2) NOT CONCURRENTLY TAKING NITRATES, NITRIC OXIDE DONORS, PHOSPHODIESTERASE INHIBITORS, OR NON-SPECIFIC PDE INHIBITORS.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RIPRETINIB

Products Affected

- QINLOCK

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

RISANKIZUMAB-RZAA

Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

RISDIPLAM

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

RITUXIMAB AND HYALURONIDASE HUMAN-SQ

Products Affected

- RITUXAN HYCELA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PATIENT HAS RECEIVED OR WILL RECEIVE AT LEAST ONE FULL DOSE OF A RITUXIMAB PRODUCT BY INTRAVENOUS INFUSION PRIOR TO INITIATION OF RITUXIMAB AND HYALURONIDASE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RITUXIMAB-ABBS

Products Affected

- TRUXIMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, GPA, MPA: 12 MO. CLL: 6 MO.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RITUXIMAB-ARRX

Products Affected

- RIABNI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	RA: INITIAL: 6 MO, RENEWAL: 12 MO. NHL, WG, MPA: 12 MO. CLL: 6 MO.
Other Criteria	RA: INITIAL: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RITUXIMAB-PVVR

Products Affected

- RUXIENCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RA: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. NHL, CLL: PRESCRIBED BY OR IN CONSULTATION WITH AN ONCOLOGIST.
Coverage Duration	NHL, GPA, MPA: 12 MONTHS. CLL: 6 MONTHS. RA: INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF ANY TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: RA: CONTINUES TO BENEFIT FROM THE MEDICATION. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ROMIPLOSTIM

Products Affected

- NPLATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	IMMUNE THROMBOCYTOPENIA (ITP): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEMATOLOGIST OR IMMUNOLOGIST.
Coverage Duration	ITP: INITIAL: 4 MO, RENEWAL: 12 MO. HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME: 12 MO.
Other Criteria	ITP: INITIAL: TRIAL OF OR CONTRAINDICATION TO CORTICOSTEROIDS, IMMUNOGLOBULINS, OR AN INSUFFICIENT RESPONSE TO SPLENECTOMY. RENEWAL: CLINICAL RESPONSE TO THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ROMOSOZUMAB

Products Affected

- EVENITY SUBCUTANEOUS SYRINGE 105 MG/1.17 ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>POSTMENOPAUSAL OSTEOPOROSIS: 1) HAS NOT RECEIVED A TOTAL OF 12 MONTHS OF EVENITY TREATMENT, 2) ONE OF THE FOLLOWING: (A) HIGH RISK FOR FRACTURES DEFINED AS ONE OF THE FOLLOWING: (I) HISTORY OF OSTEOPOROTIC (I.E., FRAGILITY, LOW TRAUMA) FRACTURE(S), (II) 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, USE OF GNRH ANALOGS SUCH AS NAFARELIN, ETC.), (III) NO PRIOR TREATMENT FOR OSTEOPOROSIS AND FRAX SCORE OF AT LEAST 20% FOR ANY MAJOR FRACTURE OR OF AT LEAST 3% FOR HIP FRACTURE, (B) 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), OR (C) TRIAL OF, INTOLERANCE TO, OR A CONTRAINDICATION TO A BISPHOSPHONATE.</p>
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	

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

ROPEGINTERFERON ALFA-2B-NJFT

Products Affected

- BESREMI

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

RUCAPARIB

Products Affected

- RUBRACA

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

RUXOLITINIB

Products Affected

- JAKAFI

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

SAFINAMIDE

Products Affected

- XADAGO

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

SAPROPTERIN

Products Affected

- *sapropterin oral tablet, soluble*

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

SARILUMAB

Products Affected

- KEVZARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	RA: INITIAL: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SATRALIZUMAB-MWGE

Products Affected

- ENSPRYNG

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

SEBELIPASE ALFA

Products Affected

- KANUMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<p>LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY: INITIAL: DIAGNOSIS CONFIRMED BY 1) PRESENCE OF CLINICAL FEATURES (E.G., HEPATOMEGALY, ELEVATED SERUM TRANSAMINASES, DYSLIPIDEMIA, SPLENOMEGALY), AND 2) ONE OF THE FOLLOWING: (A) BLOOD TEST INDICATING LOW OR ABSENT LEVELS OF LAL ENZYME ACTIVITY, (B) DRIED BLOOD SPOT TEST INDICATING LOW OR ABSENT LAL ENZYME ACTIVITY, OR (C) GENETIC TEST INDICATING THE BI-ALLELIC PRESENCE OF ALTERED LIPA GENE(S).</p>
Age Restrictions	
Prescriber Restrictions	<p>LAL DEFICIENCY: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, HEPATOLOGIST, GASTROENTEROLOGIST, MEDICAL GENETICIST, LIPIDOLOGIST, OR METABOLIC SPECIALIST.</p>
Coverage Duration	<p>LAL DEFICIENCY: INITIAL: 6 OR 12 MONTHS, SEE OTHER CRITERIA. RENEWAL: 12 MONTHS</p>

PA Criteria	Criteria Details
Other Criteria	<p>LAL DEFICIENCY: INITIAL: RAPIDLY PROGRESSIVE LAL DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE: 12 MONTHS. LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: 6 MONTHS. RENEWAL: LAL DEFICIENCY PRESENTING AFTER THE FIRST 6 MONTHS OF LIFE AND NOT CONSIDERED RAPIDLY PROGRESSIVE: IMPROVEMENT IN ONE OF THE FOLLOWING CLINICAL PARAMETERS DURING THE PAST 6 MONTHS: (1) A RELATIVE REDUCTION FROM BASELINE IN LDL-C, NON-HDL-C, OR TRIGLYCERIDES, (2) NORMALIZATION OF ASPARTATE AMINOTRANSFERASE (AST) BASED ON AGE- AND GENDER-SPECIFIC NORMAL RANGES, OR (3) DECREASE IN LIVER FAT CONTENT COMPARED TO BASELINE ASSESSED BY ABDOMINAL IMAGING.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SECUKINUMAB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): 1) C-REACTIVE PROTEIN (CRP) LEVELS ABOVE THE UPPER LIMIT OF NORMAL, OR 2) SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI).
Age Restrictions	
Prescriber Restrictions	INITIAL: PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST OR A DERMATOLOGIST. ANKYLOSING SPONDYLITIS (AS), NR-AXSPA, ENTHESITIS-RELATED ARTHRITIS (ERA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS

PA Criteria	Criteria Details
Other Criteria	INITIAL: PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTI-RHEUMATIC DRUG). AS, NR-AXSPA: TRIAL OF OR CONTRAINDICATION TO AN NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG). ERA: TRIAL OF OR CONTRAINDICATION TO ONE NSAID, SULFASALAZINE, OR METHOTREXATE. RENEWAL: PSO, PSA, AS, NR-AXSPA, ERA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SELEXIPAG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: 1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION WITH THE FOLLOWING PARAMETERS: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND 2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS

PA Criteria	Criteria Details
Other Criteria	<p>PAH: INITIAL: WHO FC II-III SYMPTOMS: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING AGENTS, EACH FROM A DIFFERENT DRUG CLASS: 1) FORMULARY VERSION OF AN ORAL ENDOTHELIAL RECEPTOR ANTAGONIST, 2) FORMULARY VERSION OF AN ORAL PHOSPHODIESTERASE TYPE-5 INHIBITOR, OR 3) FORMULARY VERSION OF AN ORAL CGMP STIMULATOR. WHO FC III SYMPTOMS AND EVIDENCE OF RAPID PROGRESSION OR POOR PROGNOSIS, WHO FC IV SYMPTOMS: NO STEP. RENEWAL: 1) IMPROVEMENT FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST, OR 2) REMAINED STABLE FROM BASELINE IN THE 6-MINUTE WALK DISTANCE TEST AND WHO FC HAS IMPROVED OR REMAINED STABLE.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SELINEXOR

Products Affected

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

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

SELPERCATINIB

Products Affected

- RETEVMO ORAL CAPSULE 40 MG,
80 MG

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

SELUMETINIB

Products Affected

- KOSELUGO ORAL CAPSULE 10 MG,
25 MG

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

SIPONIMOD

Products Affected

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

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

SODIUM OXYBATE

Products Affected

- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: ALL INDICATIONS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.
Coverage Duration	INITIAL 6 MONTHS. RENEWAL: 12 MONTHS
Other Criteria	INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: 1) NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT, 2) FOR PATIENTS 18 YEARS OR OLDER: TRIAL OF OR CONTRAINDICATION TO THE FORMULARY VERSION OF MODAFINIL, ARMODAFINIL, PITOLISANT OR SOLRIAMFETOL AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY, AND 3) FOR PATIENTS 7 TO 17 YEARS OF AGE: TRIAL OF OR CONTRAINDICATION TO ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. CATAPLEXY IN NARCOLEPSY: NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT. RENEWAL (ALL INDICATIONS): 1) SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE, AND 2) NOT CURRENTLY TAKING A SEDATIVE HYPNOTIC AGENT.
Indications	All FDA-approved Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

SOFOSBUVIR/VELPATASVIR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HCV RNA LEVEL WITHIN PAST 6 MONTHS
Age Restrictions	
Prescriber Restrictions	PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, INFECTIOUS DISEASE SPECIALIST, PHYSICIAN SPECIALIZING IN THE TREATMENT OF HEPATITIS (HEPATOLOGIST), OR A SPECIALLY TRAINED GROUP SUCH AS ECHO (EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES) MODEL.
Coverage Duration	CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE.
Other Criteria	1) CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD/IDSA GUIDANCE, 2) NOT CONCURRENTLY TAKING ANY OF THE FOLLOWING MEDICATIONS: AMIODARONE, CARBAMAZEPINE, PHENYTOIN, PHENOBARBITAL, OXCARBAZEPINE, RIFAMPIN, RIFABUTIN, RIFAPENTINE, CYCLOSPORINE, PITAVASTATIN, PRAVASTATIN (DOSES ABOVE 40MG), ROSUVASTATIN, METHOTREXATE, MITOXANTRONE, IMATINIB, IRINOTECAN, LAPATINIB, SULFASALAZINE, TOPOTECAN, OR HIV REGIMEN THAT CONTAINS EFAVIRENZ, ATAZANAVIR, LOPINAVIR, TIPRANAVIR/RITONAVIR, SOVALDI (AS A SINGLE AGENT), EPCLUSA, HARVONI, ZEPATIER, OR MAVYRET, AND 3) DOES NOT HAVE MODERATE OR SEVERE HEPATIC IMPAIRMENT (CHILD-PUGH B OR C).
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

SOLRIAMFETOL

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR SPECIALIST IN SLEEP MEDICINE.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: EDS IN NARCOLEPSY: TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL, AND ONE OTHER GENERIC STIMULANT INDICATED FOR EDS IN NARCOLEPSY. EDS IN OBSTRUCTIVE SLEEP APNEA (OSA): TRIED THE FORMULARY VERSION OF MODAFINIL OR ARMODAFINIL. RENEWAL: EDS IN NARCOLEPSY OR OSA: SUSTAINED IMPROVEMENT OF SYMPTOMS COMPARED TO BASELINE.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SOMATROPIN - NORDITROPIN

Products Affected

- NORDITROPIN FLEXPRO

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES.
Required Medical Information	INITIAL: PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD), IDIOPATHIC SHORT STATURE (ISS), SMALL FOR GESTATIONAL AGE (SGA), TURNER SYNDROME (TS), NOONAN SYNDROME: HEIGHT AT LEAST 2 STANDARD DEVIATIONS (SD) BELOW THE MEAN HEIGHT FOR NORMAL CHILDREN OF THE SAME AGE AND GENDER. PRADER WILLI SYNDROME (PWS): CONFIRMED GENETIC DIAGNOSIS.
Age Restrictions	
Prescriber Restrictions	INITIAL/RENEWAL: PRESCRIBED BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: ADULT GHD: GROWTH HORMONE DEFICIENCY ALONE OR ASSOCIATED WITH MULTIPLE HORMONE DEFICIENCIES (HYPOPITUITARISM), AS A RESULT OF PITUITARY DISEASES, HYPOTHALAMIC DISEASE, SURGERY, RADIATION THERAPY, TRAUMA, OR CONTINUATION OF THERAPY FROM CHILDHOOD ONSET GROWTH HORMONE DEFICIENCY. PEDIATRIC GHD, ISS, SGA, TS, NOONAN SYNDROME: OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. RENEWAL: PEDIATRIC GHD: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND OR PATIENT HAS NOT COMPLETED PREPUBERTALGROWTH. ISS, SGA, TS, NOONAN SYNDROME: 1) IMPROVEMENT WHILE ON THERAPY (I.E., INCREASED HEIGHT OR INCREASED GROWTH VELOCITY), AND 2) OPEN EPIPHYSES AS CONFIRMED BY RADIOGRAPH OF THE WRIST AND HAND. PWS: IMPROVEMENT IN BODY COMPOSITION.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

SOMATROPIN - SEROSTIM

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: ATHLETIC ENHANCEMENT, ANTI-AGING PURPOSES
Required Medical Information	INITIAL: HIV/WASTING: MEETS ONE OF THE FOLLOWING CRITERIA FOR WEIGHT LOSS: 1) 10% UNINTENTIONAL WEIGHT LOSS OVER 12 MONTHS, 2) 7.5% UNINTENTIONAL WEIGHT LOSS OVER 6 MONTHS, 3) 5% BODY CELL MASS (BCM) LOSS WITHIN 6 MONTHS, 4) BODY CELL MASS (BCM) LESS THAN 35% (MEN) OF TOTAL BODY WEIGHT AND BODY MASS INDEX (BMI) LESS THAN 27 KG PER METER SQUARED, 5) BCM LESS THAN 23% (WOMEN) OF TOTAL BODY WEIGHT AND A BODY MASS INDEX (BMI) LESS THAN 27 KG PER METER SQUARED, OR 6) BMI LESS THAN 18.5 KG PER METER SQUARED.
Age Restrictions	
Prescriber Restrictions	HIV/WASTING: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST, NUTRITIONAL SUPPORT SPECIALIST, OR INFECTIOUS DISEASE SPECIALIST.
Coverage Duration	INITIAL/RENEWAL: 3 MONTHS.
Other Criteria	HIV/WASTING: INITIAL: 1) CURRENTLY ON HIV ANTIRETROVIRAL THERAPY, AND 2) INADEQUATE RESPONSE TO ONE PREVIOUS THERAPY (E.G., MEGACE, APPETITE STIMULANTS, ANABOLIC STEROIDS). RENEWAL: 1) CURRENTLY ON HIV ANTIRETROVIRAL THERAPY, AND 2) CLINICAL BENEFIT IN MUSCLE MASS AND WEIGHT.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

SONIDEGIB

Products Affected

- ODOMZO

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

SORAFENIB

Products Affected

- *sorafenib*

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

SOTORASIB

Products Affected

- LUMAKRAS

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

STIRIPENTOL

Products Affected

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

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

SUNITINIB

Products Affected

- *sunitinib*

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

TADALAFIL

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

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

TALAZOPARIB

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 MONTHS
Other Criteria	PATIENT HAS BEEN TREATED WITH CHEMOTHERAPY IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING. PATIENTS WITH HORMONE RECEPTOR (HR)-POSITIVE BREAST CANCER MUST HAVE ADDITIONAL PRIOR TREATMENT WITH ENDOCRINE THERAPY OR BE CONSIDERED INAPPROPRIATE FOR ENDOCRINE THERAPY.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TALIMOGENE

Products Affected

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

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

TASIMELTEON

Products Affected

- HETLIOZ
- HETLIOZ LQ

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

TAZEMETOSTAT

Products Affected

- TAZVERIK

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

TBO-FILGRASTIM

Products Affected

- GRANIX

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

TEBENTAFUSP-TEBN

Products Affected

- KIMMTRAK

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

TEDUGLUTIDE

Products Affected

- GATTEX 30-VIAL

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

TELOTRISTAT

Products Affected

- XERMELO

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

TEPOTINIB

Products Affected

- TEPMETKO

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

TEPROTUMUMAB-TRBW

Products Affected

- TEPEZZA

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

TERIFLUNOMIDE

Products Affected

- AUBAGIO

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

TERIPARATIDE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

TESAMORELIN

Products Affected

- EGRIFTA SV

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

TESTOSTERONE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: MALE HYPOGONADISM: CONFIRMED BY: 1) AT LEAST TWO MORNING TOTAL SERUM TESTOSTERONE LEVELS OF LESS THAN 300 NG/DL TAKEN ON SEPARATE OCCASIONS WHILE IN A FASTED STATE, OR 2) FREE SERUM TESTOSTERONE LEVEL OF LESS THAN 5 PG/ML.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	MALE HYPOGONADISM: INITIAL/RENEWAL:12 MO. ALL OTHER INDICATIONS: LIFETIME OF MEMBERSHIP IN PLAN.
Other Criteria	RENEWAL: MALE HYPOGONADISM: IMPROVED SYMPTOMS COMPARED TO BASELINE AND TOLERANCE TO TREATMENT.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TETRABENAZINE

Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	HUNTINGTONS DISEASE: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST
Coverage Duration	12 MONTHS
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TEZACAFTOR/IVACAFTOR

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CYSTIC FIBROSIS (CF): INITIAL: CONFIRMED MUTATION IN CFTR GENE ACCEPTABLE FOR THE TREATMENT OF CYSTIC FIBROSIS.
Age Restrictions	
Prescriber Restrictions	CF: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST OR CYSTIC FIBROSIS EXPERT
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: LIFETIME
Other Criteria	CF: RENEWAL: MAINTAINED, IMPROVED, OR DEMONSTRATED LESS THAN EXPECTED DECLINE IN FEV1 OR BODY MASS INDEX (BMI), OR REDUCTION IN NUMBER OF PULMONARY EXACERBATIONS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

THALIDOMIDE

Products Affected

- THALOMID

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

TILDRAKIZUMAB-ASMN

Products Affected

- ILUMYA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PLAQUE PSORIASIS (PSO): INITIAL: PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.
Age Restrictions	
Prescriber Restrictions	PSO: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST.
Coverage Duration	INITIAL: 6 MONTHS, RENEWAL: 12 MONTHS.
Other Criteria	PSO: INITIAL: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, COSENTYX, STELARA, ENBREL. RENEWAL: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TISOTUMAB VEDOTIN-TFTV

Products Affected

- TIVDAK

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

TIVOZANIB

Products Affected

- FOTIVDA

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

TOCILIZUMAB IV

Products Affected

- ACTEMRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	INITIAL: RHEUMATOID ARTHRITIS (RA), POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): PRESCRIBED BY OR IN CONSULTATION WITH A RHEUMATOLOGIST, DERMATOLOGIST, OR IMMUNOLOGIST.
Coverage Duration	INITIAL: RA, PJIA, SJIA, GCA: 6 MONTHS. CRS: 1 MONTH. RENEWAL: RA, PJIA, SJIA, GCA: 12 MONTHS.
Other Criteria	INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). RENEWAL: RA, PJIA, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

TOCILIZUMAB SQ

Products Affected

- ACTEMRA
- ACTEMRA ACTPEN

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

PA Criteria	Criteria Details
Other Criteria	<p>INITIAL: RA: ONE OF THE FOLLOWING: 1) TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ, OR 2) TRIAL OF A TNF INHIBITOR AND PHYSICIAN HAS INDICATED THE PATIENT CANNOT USE A JAK INHIBITOR DUE TO THE BLACK BOX WARNING FOR INCREASED RISK OF MORTALITY, MALIGNANCIES, AND SERIOUS CARDIOVASCULAR EVENTS. PJIA: TRIAL OF OR CONTRAINDICATION TO TWO OF THE FOLLOWING PREFERRED AGENTS: HUMIRA, ENBREL, XELJANZ IR. SJIA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). SSC-ILD: DOES NOT HAVE OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE (E.G., CONNECTIVE TISSUE DISEASE, DRUG TOXICITY, ASBESTOS OR BERYLLIUM EXPOSURE, HYPERSENSITIVITY PNEUMONITIS). RENEWAL: RA, PJIA, SJIA: CONTINUES TO BENEFIT FROM THE MEDICATION. SSC-ILD: CLINICAL MEANINGFUL IMPROVEMENT OR MAINTENANCE IN ANNUAL RATE OF DECLINE.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TOFACITINIB

Products Affected

- XELJANZ
- XELJANZ XR

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

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

TOLVAPTAN

Products Affected

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLETS, SEQUENTIAL

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

TOPICAL TRETINOIN

Products Affected

- ALTRENO
- *tretinoin*

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

TRAMETINIB

Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

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

TRASTUZUMAB HYALURONIDASE

Products Affected

- HERCEPTIN HYLECTA

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

TRASTUZUMAB-ANNS

Products Affected

- KANJINTI

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

TRASTUZUMAB-DKST

Products Affected

- OGIVRI

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

TRASTUZUMAB-DTTB

Products Affected

- ONTRUZANT

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

TRASTUZUMAB-PKRB

Products Affected

- HERZUMA

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

TRASTUZUMAB-QYYP

Products Affected

- TRAZIMERA

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

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) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND (2) NYHA-WHO FUNCTIONAL CLASS (FC) III-IV SYMPTOMS. PULMONARY HYPERTENSION-INTERSTITIAL LUNG DISEASE (PH-ILD): CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: (1) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, (2) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND (3) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) OF 15 MMHG OR LESS.</p>
Age Restrictions	
Prescriber Restrictions	INITIAL: PAH, PH-ILD: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	INITIAL: PAH: 12 MONTHS, PH-ILD: 6 MONTHS. RENEWAL: PAH, PH-ILD: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<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 STIMULATOR. 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>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TREPROSTINIL INJECTABLE

Products Affected

- *treprostinil sodium*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH): INITIAL: (1) CONFIRMATORY DIAGNOSIS BASED ON RIGHT HEART CATHETERIZATION: A) MEAN PULMONARY ARTERY PRESSURE (PAP) GREATER THAN 20 MMHG, B) PULMONARY CAPILLARY WEDGE PRESSURE (PCWP) 15 MMHG OR LESS, AND C) PULMONARY VASCULAR RESISTANCE (PVR) 3 WOOD UNITS OR GREATER, AND (2) NYHA-WHO FUNCTIONAL CLASS (FC) II-IV SYMPTOMS.
Age Restrictions	
Prescriber Restrictions	PAH: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A CARDIOLOGIST OR PULMONOLOGIST.
Coverage Duration	PAH: INITIAL AND RENEWAL: 12 MONTHS
Other Criteria	PAH: INITIAL: 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 STIMULATOR. RENEWAL: 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.

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

TRIENTINE

Products Affected

- *trientine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	WILSONS DISEASE: INITIAL: KNOWN FAMILY HISTORY OF WILSONS DISEASE OR PHYSICAL EXAMINATION CONSISTENT WITH WILSONS DISEASE. CONFIRMATION OF ONE OF THE FOLLOWING: 1) PLASMA COPPER-PROTEIN CERULOPLASMIN LESS THAN 20 MG/DL, 2) LIVER BIOPSY POSITIVE FOR AN ABNORMALLY HIGH CONCENTRATION OF COPPER (GREATER THAN 250 MCG/G DRY WEIGHT) OR THE PRESENCE OF KAYSER-FLEISCHER RINGS, OR 3) CONFIRMATION BY GENETIC TESTING FOR ATP7B MUTATIONS.
Age Restrictions	
Prescriber Restrictions	WILSONS DISEASE: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 12 MONTHS, RENEWAL: LIFETIME.
Other Criteria	WILSONS DISEASE: INITIAL: TRIAL OF OR CONTRAINDICATION TO FORMULARY VERSION OF PENICILLAMINE (DEPEN). RENEWAL: PATIENT CONTINUES TO BENEFIT FROM THE MEDICATION.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TRIFLURIDINE/TIPIRACIL

Products Affected

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

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

TRIPTORELIN-TRELSTAR

Products Affected

- TRELSTAR INTRAMUSCULAR
SUSPENSION FOR
RECONSTITUTION

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

TRIPTORELIN-TRIPTODUR

Products Affected

- TRIPTODUR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): INITIAL: FEMALES: ELEVATED LEVELS OF FOLLICLE-STIMULATING HORMONE (FSH) GREATER THAN 4.0 MIU/ML AND LUTEINIZING HORMONE (LH) LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS. MALES: ELEVATED LEVELS OF FSH GREATER THAN 5.0 MIU/ML AND LH LEVEL GREATER THAN 0.2 TO 0.3 MIU/ML AT DIAGNOSIS.
Age Restrictions	
Prescriber Restrictions	CPP: INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PEDIATRIC ENDOCRINOLOGIST.
Coverage Duration	INITIAL/RENEWAL: 12 MONTHS.

PA Criteria	Criteria Details
Other Criteria	<p>CPP: INITIAL: FEMALES: 1) YOUNGER THAN 8 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR BREAST DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). MALES: 1) YOUNGER THAN 9 YEARS OF AGE AT ONSET OF CPP, AND 2) DOCUMENTATION OF PUBERTAL STAGING USING THE TANNER SCALE FOR GENITAL DEVELOPMENT (STAGE 2 OR ABOVE) AND PUBIC HAIR GROWTH (STAGE 2 OR ABOVE). RENEWAL: 1) TANNER SCALE STAGING AT INITIAL DIAGNOSIS OF CPP HAS STABILIZED OR REGRESSED DURING THREE SEPARATE MEDICAL VISITS IN THE PREVIOUS YEAR, AND 2) PATIENT HAS NOT REACHED ACTUAL AGE WHICH CORRESPONDS TO CURRENT PUBERTAL AGE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.</p>
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TUCATINIB

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

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

UBROGEPANT

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	PA Criteria: Pending CMS Approval
Required Medical Information	PA Criteria: Pending CMS Approval
Age Restrictions	PA Criteria: Pending CMS Approval
Prescriber Restrictions	PA Criteria: Pending CMS Approval
Coverage Duration	PA Criteria: Pending CMS Approval
Other Criteria	PA Criteria: Pending CMS Approval
Indications	PA Criteria: Pending CMS Approval
Off Label Uses	PA Criteria: Pending CMS Approval
Part B Prerequisite	No

USTEKINUMAB

Products Affected

- STELARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	INITIAL: PLAQUE PSORIASIS (PSO): PSORIASIS COVERING 3 PERCENT OR MORE OF BODY SURFACE AREA OR PSORIATIC LESIONS AFFECTING THE HANDS, FEET, GENITAL AREA, OR FACE.
Age Restrictions	
Prescriber Restrictions	INITIAL: PSORIATIC ARTHRITIS (PSA): PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST OR RHEUMATOLOGIST. PSO: PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST. CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	INITIAL: PSA: TRIAL OF OR CONTRAINDICATION TO ONE DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG). PSO: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A PUVA (PHOTOTHERAPY ULTRAVIOLET LIGHT A), UVB (ULTRAVIOLET LIGHT B), TOPICAL CORTICOSTEROIDS, CALCIPOTRIENE, ACITRETIN, METHOTREXATE, OR CYCLOSPORINE. CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. RENEWAL: PSA, PSO: CONTINUES TO BENEFIT FROM THE MEDICATION.

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

USTEKINUMAB IV

Products Affected

- STELARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	CROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): PRESCRIBED BY OR IN CONSULTATION WITH A GASTROENTEROLOGIST.
Coverage Duration	2 MONTHS
Other Criteria	CD, UC: TRIAL OF OR CONTRAINDICATION TO ONE CONVENTIONAL THERAPY SUCH AS A CORTICOSTEROID (E.G., BUDESONIDE, METHYLPREDNISOLONE), AZATHIOPRINE, MERCAPTOPYRINE, METHOTREXATE, OR MESALAMINE. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION AND MAY BE COVERED UNDER MEDICARE PART B OR D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VALBENZAZINE

Products Affected

- INGREZZA
- INGREZZA INITIATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	TARDIVE DYSKINESIA (TD): PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST, PSYCHIATRIST, OR MOVEMENT DISORDER SPECIALIST.
Coverage Duration	12 MONTHS
Other Criteria	TD: 1) PRIOR HISTORY OF USING AGENTS THAT CAUSE TARDIVE DYSKINESIA, AND 2) TRIAL OF OR CONTRAINDICATION TO THE PREFERRED AGENT: AUSTEDO.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VANDETANIB

Products Affected

- CAPRELSA ORAL TABLET 100 MG,
300 MG

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

VEMURAFENIB

Products Affected

- ZELBORAF

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

VENETOCLAX

Products Affected

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

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

VESTRONIDASE ALFA VJBK

Products Affected

- MEPSEVII

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	MUCOPOLYSACCHARIDOSIS VII (MPS VII): INITIAL: PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN SPECIALIZING IN GENETIC OR METABOLIC DISORDERS.
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 MONTHS.
Other Criteria	MPS VII: INITIAL: 1) PATIENT HAS NOT UNDERGONE SUCCESSFUL BONE MARROW OR STEM CELL TREATMENT FOR MPS VII, 2) LIMITATION IN MOBILITY, BUT REMAINS SUFFICIENTLY AMBULATORY, AND 3) DIAGNOSIS OF MPS VII CONFIRMED BY ALL OF THE FOLLOWING: A) URINARY GAG (GLYCOSAMINOGLYCAN) LEVEL IS 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.

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

VIGABATRIN

Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	REFRACTORY COMPLEX PARTIAL SEIZURES (CPS), INFANTILE SPASMS: PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST.
Coverage Duration	12 MONTHS
Other Criteria	CPS: 1) TRIAL OF OR CONTRAINDICATION TO TWO ANTIEPILEPTIC AGENTS AND 2) BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS. INFANTILE SPASMS: BENEFITS OUTWEIGH THE POTENTIAL FOR VISION LOSS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VISMODEGIB

Products Affected

- ERIVEDGE

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

VORICONAZOLE SUSPENSION

Products Affected

- *voriconazole oral suspension for reconstitution*

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

ZANUBRUTINIB

Products Affected

- BRUKINSA

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

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