Prior Authorization Criteria
Health Alliance Plan 2023
Date Effective: 12/01/2023

AAT DEFICIENCY

Products Affected

- Aralast NP
- Glassia
- Prolastin-C
- Zemaira

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of severe congenital A1-PI deficiency who have clinically evident emphysema, weight, A1-PI phenotype, A1-PI baseline level
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a pulmonologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACTINIC KERATOSIS

Products Affected

- diclofenac sodium topical gel 3 %

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Prior use of 5% fluorouracil topical and 5% imiquimod topical, unless contraindicated.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADAPALENE

Products Affected

- adapalene topical cream
- adapalene topical gel 0.3 %
- adapalene topical gel with pump
- adapalene topical solution
- adapalene topical swab

PA Criteria	Criteria Details
Exclusion Criteria	Not approved when used to treat photo aging.
Required Medical Information	Diagnosis, previous treatments, and response therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have failure, intolerance, or contraindication to tretinoin
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADBRY

Products Affected

- Adbry

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used and result of prior therapy. If continuation, response to tralokinumab with documented reduction in number of acute exacerbations.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information
Prescriber Restrictions	Prescribing limited to an allergist, immunologist, pulmonologist, otolaryngologist or dermatologist.
Coverage Duration	3 years
Other Criteria	For atopic dermatitis: trial of at least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADEMPAS

Products Affected

- Adempas

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis, documentation of response to any prior therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by pulmonologist or cardiologist.
Coverage Duration	3 year
Other Criteria	For WHO Group 1 diagnosis, patient must have a history of taking or contraindication to sildenafil (Revatio).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADLARITY

Products Affected

- Adlarity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments, and response therapy
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Must have a intolerance, contraindication, or medical reason the tablets are not acceptable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AFINITOR

Products Affected

- everolimus (antineoplastic)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES, AND TREATMENT RESPONSE
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST OR NEUROLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AIMOVIG

Products Affected

- Aimovig Autoinjector

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried, and outcome. Member has been evaluated for and does not have medication overuse headache.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Must be prescribed by or in consultation with a headache specialist, pain management specialist or neurologist.
Coverage Duration	1 year
Other Criteria	Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AJOVY

Products Affected

- Ajovy Autoinjector
- Ajovy Syringe

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried, and outcome. Member has been evaluated for and does not have medication overuse headache.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with a headache specialist, pain management specialist or neurologist.
Coverage Duration	1 year
Other Criteria	Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALK POSITIVE TYROSINE KINASE INHIBITORS

Products Affected

- Alecensa
- Xalkori
- Zykadia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other treatments tried and outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALUNBRIG

Products Affected

- Alunbrig

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Metastatic non-small cell lung cancer (NSCLC): must be ALK-positive, as detected by an approved test.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	5 years
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AMIFAMPRIDINE

Products Affected

- Firdapse

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Must have a documented diagnosis of Lamber-Eaton with electrodiagnostic studies including repetitive nerve stimulation and anti-P/Q-type voltage-gated calcium channel (VGCC) antibody testing to confirm the diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANALEPTIC

Products Affected

- armodafinil

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Excessive sleepiness due to SWSD defined as the patient is working at least 5 overnight shifts per month. As adjunctive/augmentation treatment for depression in the adult if the patient is concurrently receiving other medication therapy for depression.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANTIDEPRESSANTS

Products Affected

- Auvelity
- Drizalma Sprinkle oral capsule, delayed rel sprinkle 20 mg, 30 mg, 40 mg, 60 mg
- Fetzima
- Trintellix
- Viibryd oral tablets,dose pack 10 mg (7)-20 mg (23)
- vilazodone

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES TRIED AND FAILED
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	For treatment of major depressive disorder (MDD), must have tried two generic antidepressants from different classes: SSRIs, SNRIs, TCAs, NOREPINEPHRINE-DOPAMINE REUPTAKE INHIBITORS, or NORADRENERGIC and SPECIFIC SEROTONERGIC ANTIDEPRESSANTS. Examples include: sertraline, citalopram, escitalopram, fluoxetine, paroxetine, venlafaxine, duloxetine, bupropion, amitriptyline, doxepin, etc.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANTIPSYCHOTICS

Products Affected

- Abilify Maintena
- asenapine maleate
- Caplyta
- Fanapt
- Invega Hafyera
- Invega Sustenna
- Invega Trinza
- Rexulti oral tablet
- Secuado
- Versacloz
- Vraylar oral capsule
- Vraylar oral capsule,dose pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and treatement history.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	For BIPOLAR DISORDER or SCHIZOPHRENIA, documentation of diagnosis, and treatment failure with two atypical anti-psychotics: ZIPRASIDONE, RISPERIDONE, QUETIAPINE, OLANZAPINE, CLOZAPINE, ARIPIPRAZOLE) or rationale as to why alternatives are not suitable. For treatment of major depressive disorder (MDD), must have tried generic antidepressants from at least two different classes: SSRIs, SNRIs, TCAs, NOREPINEPHRINE-DOPAMINE REUPTAKE INHIBITORS, or NORADRENERGIC and SPECIFIC SEROTONERGIC ANTIDEPRESSANTS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

APREPITANT

Products Affected

- aprepitant

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For use with highly and moderately-emetogenic chemotherapy, provide the chemotherapy regimen including drug, dose, and frequency. Ondansetron is preferred for post-operative nausea/vomiting (PONV) prophylaxis. When aprepitant is used for PONV prophylaxis, provide rationale as to why ondansetron is not a suitable alternative.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Request will also be reviewed for coverage under part B versus part D.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	1 YEAR AT A TIME
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AURYXIA

Products Affected

- Auryxia

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for treatment of iron deficiency anemia in patients with ESRD on dialysis.
Required Medical Information	Diagnosis, CKD/ESRD Stage, prior therapy used and response to prior therapy. Required pre-treatment testing for hyperphosphatemia: serum calcium and phosphorus, serum creatinine and eGFR.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a nephrologist.
Coverage Duration	3 year
Other Criteria	For hyperphosphatemia, documentation of prior use of calcium acetate and one other drug: sevelamer or lanthanum.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AYVAKIT

Products Affected

- Ayvakit

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to avapritinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist or gastroenterologist - or - an allergist or immunologist, as appropriate to the diagnosis.
Coverage Duration	5 years
Other Criteria	For GIST: documentation of a PDGFRA exon 18 mutation or PDGFRA D842V mutation. For AdvSM, documentation of platelet count greater than 50 X 10-9th/L.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BALVERSA

Products Affected

- Balversa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, and outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BANZEL

Products Affected

- rufinamide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state such as a neurologist.
Coverage Duration	5 years
Other Criteria	For Lennox-Gastaut Syndrome: documenation of treatment with valproate and lamotrigine with outcomes (treatment failure or intolerance).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BENLYSTA

Products Affected

- Benlysta subcutaneous syringe

PA Criteria	Criteria Details
Exclusion Criteria	Severe active lupus nephritis, active central nervous, use in combination with other biologics
Required Medical Information	Diagnosis, autoantibody testing, prior treatments including response, and SLEDAI score.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a rheumatologist or nephrologist.
Coverage Duration	6 months
Other Criteria	Failed to demonstrate adequate response to TWO standard therapies at recommended doses: corticosteroids, antimalarials, NSAIDs, and/or immunosuppressants. SLEDAI score greater than 8.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BESREMI

Products Affected

- Besremi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, and outcome
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Must have an intolerance, contraindication, or treatment failure with hydroxyurea and Peginterferon alpha-2a.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BOSULIF

Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to bosutinib. CBC and LFT lab test results are needed for continuation treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRAFTOVI

Products Affected

- Braftovi oral capsule 75 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRIVIACT

Products Affected

- Briviact oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used and result of prior therapy. If continuation, response to brivaracetam.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by neurologist.
Coverage Duration	3 years
Other Criteria	Failure of treatment with levetiracetam and ONE additional Part D formulary anticonvulsant drug.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRUKINSA

Products Affected

- Brukinsa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by hematologist/oncologist.
Coverage Duration	5 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CABOMETYX

Products Affected

- Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CALQUENCE

Products Affected

- Calquence
- Calquence (acalabrutinib mal)

PA Criteria	Criteria Details
Exclusion Criteria	NA
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by oncology
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

PA Criteria	Criteria Details
Exclusion Criteria	HISTORY OF CONGENITAL LONG QT SYNDROME
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES, TREATMENT RESPONSE
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	ECG, ELECTROLYTE(K,Mg,Ca), AND TSH MONITORING AT BASELINE, 2-4 WEEKS AND 8-12 WEEKS AFTER STARTING TREATMENT AND EVERY 3 MONTHS THEREAFTER
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CINQAIR

Products Affected

- Cinqair

PA Criteria	Criteria Details
Exclusion Criteria	Administration of reslizumab requires a specialized care setting and requires an experienced clinician prepared to manage anaphylaxis will not be approved for self-administration
Required Medical Information	Allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count
Age Restrictions	N/A
Prescriber Restrictions	Pulmonology or Immunologist
Coverage Duration	1 year
Other Criteria	Patient must be diagnosed with severe asthma, currently receiving inhaled and/or oral corticosteroid treatment, have a baseline eosinophil count of 400/mcL, have a contraindication, intolerance or failure of Nucala.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COMETRIQ

Products Affected

- Cometriq

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COPIKTRA

Products Affected

- Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CORLANOR

Products Affected

- Corlanor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For heart failure in adult patients, only: ejection fraction less than or equal to 35% AND heart rate greater than 70 beats per minute AND in sinus rhythm AND on maximally tolerated beta-blocker OR has contraindication to beta-blocker (i.e.. allergy, severe COPD limiting beta blocker usage).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a cardiologist.
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COSENTYX

Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous syringe 75 mg/0.5 mL
- Cosentyx UnoReady Pen

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other treatments tried and reasons for failure. Regular monitoring for TB required, both at baseline and during treatment
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribing limited to a rheumatologist or dermatologist.
Coverage Duration	3 year
Other Criteria	For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine and methotrexate.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COTELLIC

Products Affected

- Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed, and treatment response.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CROFELEMER

Products Affected

- Mytesi

PA Criteria	Criteria Details
Exclusion Criteria	Use when infectious diarrhea has not been ruled out
Required Medical Information	Diagnosis, use of antiretroviral therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	Infectious diarrhea needs to be ruled out prior to initiating treatment. Patient must have a history of using at least two prior treatments for diarrhea, including bismuth subsalicylate, kaolin, loperamide, or diphenoxylate/atropine.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTADROP

Products Affected

- Cystadrops

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to cysteamine.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Presribing limited to opthalmologist or corneal specialist.
Coverage Duration	1 year
Other Criteria	To start treatment, documentation of presence of corneal cystine crystal accumulation by slit lamp examination, baseline Corneal Cystine Cystal Score (CCCS) provided. For continuation: positive response to therapy (e.g., documentation showing improvement in vision with less pain and photophobia).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALIRESP

Products Affected

- roflumilast

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	For COPD, patients must meet all of the following conditions: diagnosis of severe or very severe COPD (defined as FEV-1 less than 50 based on GOLD), AND a recent history of exacerbations or ER treatments within the last 120 days, AND documented use of TWO different combinations of triple therapy (LAMA, LABA, ICS) using products such as GEQ Advair and Spiriva (or similar) and Trelegy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DAURISMO

Products Affected

- Daurismo oral tablet 100 mg, 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DAYBUE

Products Affected

- Daybue

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Rett disorder.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- deferiprone

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, length of therapy, serum ferritin concentrations and dose/weight verification, & CBC
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a contraindication to, or an inadequate response to, or have experienced clinically significant adverse effects to deferasirox.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEMSER

Products Affected

- metyrosine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and whether the patient is a candidate for surgery
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIACOMIT

Products Affected

- Diacomit

PA Criteria	Criteria Details
Exclusion Criteria	There is no clinical data to support the use of Diacomit alone to treat Dravet syndrome.
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to stiripentol.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	5 years
Other Criteria	Documentation must show co-administration of stiripentol with clobazam.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIFICID

Products Affected

- Dificid oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an infectious disease specialist
Coverage Duration	1 month
Other Criteria	History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DOPTELET

Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and platelet count.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state such as a hematologist, oncologist, or gastroenterologist.
Coverage Duration	1 month for chronic liver disease, 6 months for chronic immune thrombocytopenia.
Other Criteria	For chronic liver disease-associated thrombocytpenia, the patient must be scheduled to undergo a pre-planned medical or dental procedure with treatment beginning 10 to 13 days prior to the scheduled procedure. Patients should undergo the procedure 5 to 8 days after the last dose.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DRONABINOL

Products Affected

- dronabinol

PA Criteria	Criteria Details
Exclusion Criteria	Not covered for the treatment of pain.
Required Medical Information	Diagnosis, previous treatments, and the outcome.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For cancer related weight loss, must have a treatment failure or intolerance to megestrol.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DUPIXENT

Products Affected

- Dupixent Pen subcutaneous pen injector 200 mg/1.14 mL, 300 mg/2 mL
- Dupixent Syringe subcutaneous syringe 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used and result of prior therapy. If continuation, response to dupilumab with documented reduction in number of acute exacerbations.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribing limited to an allergist, immunologist, pulmonologist, otolaryngologist or dermatologist.
Coverage Duration	3 year
Other Criteria	For atopic dermatitis: a trial on at least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus). Immunomodulators will not be required for patients under 2 years of age. For chronic rhinosinusitis with nasal polyps (CRS with NP): documentation of inflammatory persistence for 12 weeks or longer and a trial of of a intranasal corticosteroId product (beclomethasone, fluticasone, mometasone). For asthma: blood and/or tissue eosinophil testing with documentation of a trial of an interleukine drug (montelukast, zafirlukast).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	RA/AS/JIA/JRA, prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist. PP, prescribed by or in consult w/ dermatologist.GVHD, prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center.Behcet's disease, prescribed by or in consult w/ rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist.
Coverage Duration	3 year
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first)

PA Criteria	Criteria Details
	OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic coricosteroid, immunosuppressives, Humira or an infliximab product.RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENSPRYNG

Products Affected

- Enspryng

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to satralizumab-mwge.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a neurologist or ophthalmologist.
Coverage Duration	3 years
Other Criteria	Confirmed diagnosis of neuromyelitis optica spectrum disorder (NMOSD) with a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies. Documented treatment failure with immunosuppressive therapy: corticosteroid therapy and mycophenolate.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by or in consultation with a neurologist.
Coverage Duration	5 years
Other Criteria	For Lennox-Gastaut Syndrome: documentation of use of valproate and lamotrigine and outcomes (treatment failure or intolerance). For Dravet Syndrome: documentation of use of valproate and topiramate and outcomes (treatment failure or intolerance). For refractory seizures: documentation of use of two different anti-convulsant drugs from different pharmacologic classes (valproate, topiramate, lamotrigine or similar) and outcomes (intolerance or treatment failure).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EPRONTIA

Products Affected

- Eprontia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, and outcome
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	5 Years
Other Criteria	Must have a intolerance, contraindication, or medical reason the tablet or capsule are not acceptable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERGOTAMINE DERIVATIVES

Products Affected

- dihydroergotamine nasal

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments and responses.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a headache specialist, pain management specialist or neurologist.
Coverage Duration	1 year
Other Criteria	For treatment of migraine, unless contraindicated, a trial and failure of two different triptans (covered on the formulary): one oral tablet and one other formulation, either nasal spray or injection.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERIVEDGE

Products Affected

- Erivedge

PA Criteria	Criteria Details
Exclusion Criteria	PATIENTS WHO ARE CANDIDATES FOR SURGERY OR RADIATION
Required Medical Information	DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY A ONCOLOGIST OR DERMATOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERLEADA

Products Affected

- Erleada oral tablet 240 mg, 60 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and outcome, fall risk assessment, and seizure history (if any)
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by an oncologist or urologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERYTHROPOIESIS STIMULATING AGENTS

Products Affected

- Aranesp (in polysorbate) injection solution 100 mcg/mL, 200 mcg/mL, 25 mcg/mL, 40 mcg/mL, 60 mcg/mL
- Aranesp (in polysorbate) injection syringe
- Epogen 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

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment.
Required Medical Information	Pre-treatment hemoglobin level less than 10 g/dL AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out.
Age Restrictions	N/A
Prescriber Restrictions	CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies - prescribed by an oncologist/hematologist. Surgery - Prescribed by a surgeon. HIV - Prescribed by an infectious disease specialist.
Coverage Duration	Initial: 3 months. Renewal: CKD-12 months, Non-myeloid cancers, HIV-4 months. Surgery-3 months
Other Criteria	For renewal of CKD, for dialysis patients: Hb less than 11 g/dL or physician will decrease or interrupt dose and for non-dialysis patients: Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks. For renewal of zidovudine-treated HIV, Hb is 12g/dL or less AND Zidovudine dose remains 4,200 mg/week or less and there is a measurable response after eight weeks (defined as an increase in Hb or a reduction in RBC transfusion requirements or documented dose escalation [up to max of 300 units/kg/dose])
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No

EVRYSDI

Products Affected

- Evrysdi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to risdiplam.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a pulmonologist, neurologist, orthopedist or gastroenterologist.
Coverage Duration	1 year
Other Criteria	Genetic testing to determine if the SMN1 gene is missing or damaged is required to initiate SMA treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EXKIVITY

Products Affected

- Exkivity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, and treatment response. Evidence of EGFR exon 20 insertion mutation
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a Pulmonologist or Immunologist or Allergist
Coverage Duration	3 year
Other Criteria	Patient must be diagnosed with severe asthma, currently receiving inhaled and/or oral corticosteroid treatment, AND have a baseline eosinophil count of 150 cells/mcL or greater within previous 12 months.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINTEPLA

Products Affected

- Fintepla

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to fenfluramine.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FORTEO

Products Affected

- teriparatide

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for a cumulative lifetime duration of abaloparatide and any other parathyroid hormone therapy (eg, teriparatide) of more than 2 years. Not approved for combination therapy of a PTH/PTHrP analog in combination with other osteoporosis agents.
Required Medical Information	Diagnosis, fracture history, prior therapy used and response to prior therapy. Required pretreatment testing: DXA, if not performed in the past two years: serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D), and, 24-hour urine calcium, creatinine (or fasting specimen for calcium/creatine ratio) to evaluate for baseline hypercalciuria.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an endocrinologist.
Coverage Duration	2 years
Other Criteria	Documentation of a trial on an oral bisphosphonate, or, if GI intolerant of oral bisphosphonates, use of a parenteral bisphosphonate - AND - a trial on denosumab.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FOTIVDA

Products Affected

- Fotivda

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, response to tivozanib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a specialist in hematology / oncology.
Coverage Duration	5 years
Other Criteria	Documentation of two prior lines of systemic drug therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FYCOMPA

Products Affected

- Fycompa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried, response to prior therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be prescribed by neurologist
Coverage Duration	5 years
Other Criteria	Monitor at initiation and after dose increases for serious psychiatric and/or behavioral reactions.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GALAFOLD

Products Affected

- Galafold

PA Criteria	Criteria Details
Exclusion Criteria	Not covered in combination with Fabrazyme
Required Medical Information	Confirmed diagnosis of Fabry disease and baseline renal function assessment
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a specialist in genetic disorders, or nephrologist
Coverage Duration	3 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GATTEX

Products Affected

- Gattex 30-Vial

PA Criteria	Criteria Details
Exclusion Criteria	Therapy should be discontinued in cases of intestinal malignancy.
Required Medical Information	Diagnosis, other therapies tried and treatment responses.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a gastroenterologist.
Coverage Duration	3 year
Other Criteria	For ADULT patients: A colonoscopy of the entire colon with removal of polyps must be done before initiating therapy, medical records documenting this procedure must be submitted. For PEDIATRIC patients: Perform fecal occult blood testing: if there is unexplained blood in the stool, perform colonoscopy / sigmoidoscopy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GAUCHER'S DISEASE TREATMENT

Products Affected

- Cerdelga
- miglustat

PA Criteria	Criteria Details
Exclusion Criteria	NOT APPROVED FOR TYPE II OR TYPE III GAUCHER'S DISEASE
Required Medical Information	Diagnosis. For MIGLUSTAT: rationale as to why ERT is not appropriate.
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY GENETICIST, HEMOTOLOGIST, OR METABOLIC SPECIALIST
Coverage Duration	3 YEAR
Other Criteria	USE OF MIGLUSTAT IS RESERVED FOR THOSE WHOM ENZYME REPLACEMENT THERAPY IS NOT AN OPTION
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GAVRETO

Products Affected

- Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to pralsetinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist or pulmonologist.
Coverage Duration	5 years
Other Criteria	Diagnosis of non-small cell lung cancer (NSCLC) that is verified by an FDA-approved diagnostic test to have rearranged during transfection (RET) fusion mutations.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GILOTRIF

Products Affected

- Gilotrif

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried and/or failed
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLEOSTINE

Products Affected

- Gleostine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried and/or failed
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLIMEPIRIDE

Products Affected

- glimepiride

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy and response to propr therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GRALISE

Products Affected

- Gralise oral tablet extended release 24 hr

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous treatments, including dosage and outcome of previous treatments.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a documented intolerance, contraindication to, or failure of gabapentin titrated to maximum tolerated dosage or rationale as to why gabapentin cannot be used.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GROWTH HORMONE

Products Affected

- Norditropin FlexPro
- Nutropin AQ Nuspin

PA Criteria	Criteria Details
Exclusion Criteria	PRESENCE OF CONTRAINDICATIONS TO THERAPY
Required Medical Information	DIAGNOSIS, HEIGHT AND WEIGHT, HISTORY OF GROWTH MEASUREMENT. REPLACEMENT THERAPY IN PATIENTS WITH GROWTH HORMONE DEFICIENCY WITH DIAGNOSIS CONFIRMED BY APPROPRIATE GROWTH HORMONE STIMULATION TESTING
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an an endocrinologist or nephrologist.
Coverage Duration	3 years
Other Criteria	Replacement therapy in patients with growth hormone deficiency with diagnosis confirmed by appropriate growth hormone stimulation testing.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HADLIMA

Products Affected

- adalimumab-fkjp
- Hadlima
- Hadlima PushTouch
- Hadlima(CF)
- Hadlima(CF) PushTouch

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist
Coverage Duration	3 years
Other Criteria	RA: patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). JIA/JRA: patient has tried another a non-biologic DMARD (e.g., MTX, sulfasalazine, leflunomide, NSAID) - or - biologic DMARD (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP: approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (e.g., MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional agent first) OR 2) patient has a contraindication to MTX as determined by the prescribing physician. CD: patient has tried corticosteroids (CSs), or if CSs are contraindicated, or if pt

PA Criteria	Criteria Details
	currently on CSs, or patient has tried one other agent for CD (e.g., azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR patient had ilecolonic resection or enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC: patient has tried a systemic therapy (e.g., 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS: patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Adalimumab 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. For all indications (excepting hidradenitis suppurativa), weekly dosing requires demonstration of treatment failure of every other week dosing.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HEMADY

Products Affected

- Hemady

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to dexamethasone.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Presribing limited to hematologist / oncologist.
Coverage Duration	5 years
Other Criteria	Clinical treatment plan to include combination therapy of dexamethasone with other anti-myeloma products. Dexamethasone dosing is to be in accordance with the Prescribing Information of the other anti-myeloma products used in the combination treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HEPATITIS B

Products Affected

- Baraclude oral solution
- entecavir

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HBEAG, HBV DNA QUANTITY, AND ALT LEVEL
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY A GASTROENTEROLOGIST, HEPATOLOGIST, OR INFECTIOUS DISEASE SPECIALIST
Coverage Duration	3 YEAR
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HEREDITARY ANGIOEDEMA

Products Affected

- Haegarda
- icatibant
- Orladeyo
- Sajazir
- Takhzyro

PA Criteria	Criteria Details
Exclusion Criteria	Dual prescribing of injectable and oral formulations for HAE prophylaxis are not covered to prevent risk of double-dosing.
Required Medical Information	Diagnosis and the results of immunologic laboratory testing that show low C4 and functional C1- inhibitor levels (less than the lower limits of laboratory reference ranges).
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an allergist or immunologist.
Coverage Duration	1 year
Other Criteria	For icatibant initiation: Member is 18 years of age and older, with confirmed diagnosis of HAE. To continue icatibant in patients who have treated previous acute HAE attacks with icatibant: documentation demonstrating a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity). To initiate berotralstat (Orladeyo: Member is aged 12 or older. Confirmed diagnosis of HAE. For those 18 years or older, documented use and effectiveness of on-demand treatment with icatibant (Firazyr) and that adding prophylaxis treatment is appropriate to the care plan. To initiate C1 esterase inhibitor, (Haegrada): Member is aged 6 or older. Confirmed diagnosis of HAE. For those 18 years or older, documented use and effectiveness of on-demand treatment with icatibant (Firazyr) and that adding prophylaxis treatment is appropriate to the care plan. To intiate lanadelumab-flyo (Takhzyro):): Member is aged 2 or older. Confirmed diagnosis of HAE. For those 18 years or older, documented use and effectiveness of on-demand treatment with icatibant (Firazyr) and that adding prophylaxis treatment is appropriate to the care plan.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No

HETLIOZ

Products Affected

- tasimelteon

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies and responses.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a sleep specialist or neurologist.
Coverage Duration	1 year
Other Criteria	For a diagnosis of non-24-hour sleep-wake disorder, submit sleep log through a wrist activity monitor that supports diagnosis of non-24-hour sleep-wake disorder) AND sleep study has ruled out sleep apnea and periodic limb movement disorder. For continuation, positive clinical response demonstrated by: (1) increased total nighttime sleep and, (2) decreased daytime nap duration, as determined by treating physician. For nighttime sleep disturbances in Smith-Magenis Syndrome, documentation supporting the diagnosis.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

Products Affected

- Juxtapid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, results of prior therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 year
Other Criteria	Patient must have a diagnosis of homozygous familial hypercholesterolemia. Liver function tests required at baseline and at least monthly during the first year of treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HUMIRA

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) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- Humira(CF) Pen Psor-Uv-Adol HS
- Humira(CF) Pen subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist
Coverage Duration	3 years
Other Criteria	RA: patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). JIA/JRA: patient has tried another a non-biologic DMARD (e.g., MTX, sulfasalazine, leflunomide, NSAID) - or - biologic DMARD (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP: approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (e.g., MTX,

PA Criteria	Criteria Details
	cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional agent first) OR 2) patient has a contraindication to MTX as determined by the prescribing physician. CD: patient has tried corticosteroids (CSs), or if CSs are contraindicated, or if pt currently on CSs, or patient has tried one other agent for CD (e.g., azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR patient had ilecolonic resection or enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC: patient has tried a systemic therapy (e.g., 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS: patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling. For all indications (excepting hidradenitis suppurativa), weekly dosing requires demonstration of treatment failure of every other week dosing.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IBRANCE (S)

Products Affected

- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ICLUSIG

Products Affected

- Iclusig

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	Liver function monitoring required at baseline and 3 months after initiation
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IDHIFA

Products Affected

- Idhifa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments, and outcome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IMBRUVICA

Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral suspension
- Imbruvica oral tablet 140 mg, 280 mg, 420 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be prescribed by oncologist, hematologist, or transplant specialist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INBRIJA

Products Affected

- Inbrija inhalation capsule, w/inhalation device

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to LEVODOPA ORAL INHALATION.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	1 year
Other Criteria	Required trial and failure of: 1) both carbidopa/levodopa IR and ER and, 2) at least one other Parkinson's Disease drug: entacapone, pramipexole, ropinirole, selegiline, rasagiline, or amantadine. Intention to continue use of carbidopa/levodopa.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INCRELEX

Products Affected

- Increlex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, HEIGHT AND WEIGHT MEASUREMENTS, GH LEVEL, IGF-1 LEVEL
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ENDOCRINOLOGIST
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INHALED TOBRAMYCIN

Products Affected

- Tobi Podhaler

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, therapies tried, and outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by Infectious disease specialist or pulmonologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY A ONCOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INQOVI

Products Affected

- Inqovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to decitabine / cedazuridine
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a hematologist / oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INREBIC

Products Affected

- Inrebic

PA Criteria	Criteria Details
Exclusion Criteria	Evaluate baseline thiamine levels prior to treatment initiation, do not initiate fedratinib in patients with thiamine deficiency. Replete thiamine prior to fedratinib initiation and during treatment if thiamine levels are low.
Required Medical Information	Diagnosis, Other therapies tried with treatment response, baseline thiamine level, baseline platelet level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by Hematologist / Oncologist
Coverage Duration	5 years
Other Criteria	Documented baseline platelet count of at least 50,000 per cubic milimeter.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INTERFERON ALPHA

Products Affected

- Pegasys

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	FOR HEPATITIS C: PATIENT WEIGHT, GENOTYPE, HCV-RNA QUANTITY AND DATE OF TEST, PRESENCE OF DIRRHOSIS (Y/N), TREATMENT HISTORY, HISTORY OF ANEMIA OR DEPRESSION. HEPATITIS B: HBEAG STATUS, HBV DNA QUANTITY, AND ALT LEVEL. OTHERS: DIAGNOSIS, OTHER THERAPIES TRIED AND FAILED, RESPONSE TO TREATMENT
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 YEARS FOR INDICATIONS OTHER THAN HEPATITIS C. HEPC APPROVALS FROM 12-48 WKS BASED ON DRUG REGIMEN
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IRESSA

Products Affected

- gefitinib

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, response to prior therapy
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	GEFITINIB IS COVERED AS MONOTHERAPY
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVIG

Products Affected

- Bivigam
- Flebogamma DIF
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- Octagam
- Privigen

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and response to treatments.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. Part B before Part D Step Therapy: SCIG will be reserved for members who cannot use IVIG due to poor access (on going access site issues unresolved by traditional means) - or - SCIG will be reserved for patients who continue to experience infusion reactions despite documented infusion rate adjustments and adequate pre-treatment. For Idiopathic thrombocytopenia purpura (ITP): trial and failure of oral corticosteroids at therapeutic dose (standard dosage of prednisone is 1 mg/kg/day) required. For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): trial and failure of oral corticosteroids at therapeutic dose (standard dosage of prednisone is 1-1.5 mg/kg/day) required.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

JAKAFI

Products Affected

- Jakafi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, OTHER TREATMENTS TRIED AND FAILED, CBC AT BASELINE AND PERIODICALLY AFTER INITIATION, HISTORY OF RBC TRANSFUSIONS
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a hematologist, oncologist or transplant specialist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JAYPIRCA

Products Affected

- Jaypirca

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by? hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JYNARQUE

Products Affected

- Jynarque oral tablets, sequential

PA Criteria	Criteria Details
Exclusion Criteria	History of signs or symptoms of significant liver impairment or injury
Required Medical Information	Documented diagnosis of polycystic kidney disease, ultrasound results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by endocrinology or nephrology
Coverage Duration	6 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KALYDECO

Products Affected

- Kalydeco oral granules in packet 13.4 mg, 25 mg, 50 mg, 75 mg
- Kalydeco oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and the presence of one or more specific gene mutations that the drug is FDA approved to treat.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KERENDIA

Products Affected

- Kerendia

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for serum potassium greater than 5.0 mEq/L.
Required Medical Information	Diagnosis, prior drug treatments and outcomes. Potassium level within 30 days.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an endocrinologist, nephrologist or cardiologist.
Coverage Duration	1 year
Other Criteria	INITIATION: Documented diagnosis of chronic kidney disease (CKD) associated with diabetes mellitus, Type 2 (T2D). Documentation in the medical record that the patient is currently receiving the following standard of care background therapy with the requested agent: (a) a maximally tolerated dose of angiotensin converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), or a combination medication containing an ACE inhibitor or ARB therapy - AND - (b) an antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1) - OR - (c) according to the prescriber, the patient has contraindications to both ACE and ARB drug therapy. At baseline (prior to initiation of finerenone), (a) an estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73m2 and less than 75 mL/min/1.73 m2 - AND - (b) serum potassium level less than or equal to 5.0 mEq/L. CONTINUATION: Serum potassium within 30 days. Demonstrated response of GFR with finerenone therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy
Required Medical Information	Diagnosis, other therapies tried and/or failed
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by rheumatologist or pediatrician
Coverage Duration	3 year
Other Criteria	RA initial, Trial (3 month) and failure one formulary anti-TNF agents (adalimumab, etanercept, infliximab), or medically valid rationale as to why anti-TNF agents cannot be used (e.g. congestive heart failure (NYHA class III/IV) with an ejection fraction less than or equal to 50%) . Trial (3 month) and failure to Rinvoq or medically valid rationale to avoid.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KISQALI

Products Affected

- Kisqali
- Kisqali Femara Co-Pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies previously tried, and the outcome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KORLYM

Products Affected

- Korlym

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and outcome, HbA1c
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by endocrinologist
Coverage Duration	1 year
Other Criteria	Must have trial of ketoconazole therapy or have intolerance or contraindication to this medication. Must have failed surgery or not be a candidate for surgery. For continuation of therapy patient must show an improvement in HbA1c.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KRAZATI

Products Affected

- Krazati

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, diagnostic testing for muations, prior drug treatments and outcomes.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist.
Coverage Duration	5 years
Other Criteria	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KUVAN

Products Affected

- sapropterin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. BASELINE and FOLLOW-UP phenylalanine levels.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 MONTHS FOR INITIATION, 1 YEAR FOR CONTINUATION
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LENVIMA

Products Affected

- Lenvima

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LEUKINE

Products Affected

- Leukine injection recon soln

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIBTAYO

Products Affected

- Libtayo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed, and response to prior therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by or in consultation with an oncologist or hematologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIDOCAINE TRANSDERMAL

Products Affected

- lidocaine topical adhesive patch,medicated 5 %
- lidocaine topical ointment

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LOKELMA

Products Affected

- Lokelma

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of hyperkalemia, confirmed with laboratory test within the past month.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For initiation, must have a failure, contraindication, or intolerance to sodium polystyrene sulfonate (SPS). For continuation, must show response to therapy as demonstrated by normal potassium levels and patient remains at high risk for recurrence of hyperkalemia.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LONSURF

Products Affected

- Lonsurf

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed, and treatment response
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LORBRENA

Products Affected

- Lorbrena

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUMAKRAS

Products Affected

- Lumakras

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, diagnostic testing for muations, prior drug treatments and outcomes.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist.
Coverage Duration	5 years
Other Criteria	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYBALVI

Products Affected

- Lybalvi

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for dementia-related psychosis. Not approved for patients using opioids. Not approved for patients undergoing acute opioid withdrawal.
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Psychiatrist or in consulation with psychiatrist.
Coverage Duration	5 years
Other Criteria	Demonstrated positive clinical response but with unacceptable weight gain while on single-agent olanzapine AND trial/failure of one other formulary atypical anti-psychotic (e.g., risperidone, aripiprazole, quetiapine, ziprasidone) titrated to maximum tolerated dose. Rationale for combination therapy in medical record. Patient does not have a known opioid use disorder nor is dependent on opioids for a chronic health condition. Prior to initiating LYBALVI when prescription history shows opioid fills within the last 30 days, prescriber attestation required to initiate olanzapine/samidorphine (LYBALVI): 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYNPARZA

Products Affected

- Lynparza

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES, GENETIC TESTING
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYTGOBI

Products Affected

- Lytgobi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by? hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MAVACAMTEN

Products Affected

- Camzyos

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a cardiologist
Coverage Duration	3 years
Other Criteria	Must have an intolerance, contraindication, or treatment with at least one Non-vasodilating beta-blocker (e.g. metoprolol, propranolol or atenolol) AND one Non-dihydropyridine calcium channel blocker (e.g. verapamil, diltiazem)
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEKINIST

Products Affected

- Mekinist oral recon soln
- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
Exclusion Criteria	Wild-type BRAF melanoma
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. Documentation of BRAF mutation, as detected using an FDA-approved test.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEKTOVI

Products Affected

- Mektovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	Must be used in combination with encorafenib.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

METHAMPHETAMINE

Products Affected

- methamphetamine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies previously tried and failed, and response to treatment
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For the treatment of attention deficit disorder patient must have a trial of both methylphenidate and amphetamine/dextroamphetamine or rationale as to why these treatments are not suitable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MIRVASO

Products Affected

- brimonidine topical

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis and other treatments tried and outcome.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For the treatment of acne rosacea: doxycycline (oral) and topical metronidazole.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MODAFINIL

Products Affected

- modafinil oral tablet 100 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to modafinil.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 year
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults - appprove if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome - approve. Excessive daytime sleepiness associated with narcolepsy - approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MULPLETA

Products Affected

- Mulpleta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and platelet count
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state such as a hematologist, oncologist, or gastroenterologist.
Coverage Duration	1 month
Other Criteria	Patient must be scheduled to undergo a pre-planned medical or dental procedure with treatment beginning 8 to 14 days prior to the scheduled procedure. Patients should undergo the procedure 2 to 8 days after the last dose.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MULTIPLE SCLEROSIS - INJECTABLE

Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit
- Extavia
- Plegridy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For MS diagnosis: EDSS score, relapse history, physical or cognitive disability, TB test.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state such as a neurologist.
Coverage Duration	3 year
Other Criteria	To initiate interferon beta-1a (Avonex) or peginterferon beta-1a (Plegridy): (unless contraindicated), must demonstrate a trial of injectable glatopa or glatiramer with documented treatment failure.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MULTIPLE SCLEROSIS - ORAL

Products Affected

- fingolimod
- 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)
- Mayzent
- Mayzent Starter(for 1mg maint)
- Mayzent Starter(for 2mg maint)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For MS diagnosis: EDSS score, relapse history, physical or cognitive disability.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	3 year
Other Criteria	To initiate fingolimod (Gilenya), cladribine (Mavenclad), and siponimod (Mayzent): (unless contraindicated), must demonstrate a trial of oral dimethyl fumarate (Tecfidera) and documented treatment failure. Dimethyl fumarate will not be required prior to fingolimod for patients 10-17 years of age.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MU-OPIOID RECEPTOR ANTAGONIST.

Products Affected

- Symproic

PA Criteria	Criteria Details
Exclusion Criteria	Will not be approved for cancer related pain
Required Medical Information	Documented diagnosis of opiate induced constipation (non-cancer pain)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Patient must have a trial of or contraindication to at least two different classes of laxative agents including bulk, osmotic, or stimulant laxatives.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYFEMBREE

Products Affected

- Myfembree

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medically accepted indication
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Trial of 2 oral contraceptives
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, BASELINE SERUM CALCIUM AND 25-HYDROXYVITAMIN D LEVELS
Age Restrictions	N/A
Prescriber Restrictions	MUST BE PRESCRIBED BY AN ENDOCRINOLOGIST
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAYZILAM

Products Affected

- Nayzilam

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to midazolam.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NERLYNX

Products Affected

- Nerlynx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments, and outcome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXLETOL

Products Affected

- Nexletol
- Nexlizet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to bempedoic acid (with or without ezetimibe).
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by or given in consultation with a cardiologist, endocrinologist, or physician who focuses on CV risk management and or lipid disorders.
Coverage Duration	3 year
Other Criteria	Established diagnosis of heterozygous familial hypercholesterolemia (HeFH) OR atherosclerotic cardiovascular disease (ASCVD) with history of ONE of the following (for ASCVD): Myocardial infarction (MI) OR Acute Coronary Syndrome (ACS) OR Stable or unstable angina OR Thromboembolic stroke OR Transient ischemic attack (TIA) OR Peripheral arterial disease (PAD) OR Coronary or other arterial revascularization. Patient has had a previous trial of or has a contraindication to a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) and LDL-C remains greater than 100 mg/dL with laboratory confirmation within the last 30 days. If patient cannot tolerate a high intensity statin, the patient is taking a maximally tolerated dose of any statin. If intolerate of all statins, patient has had a trial of ezetimbe, unless contraindicated, and LDL-C remains greater than 100 mg/dL with laboratory confirmation within the last 30 days. Patient will continue taking the maximally tolerated statin (unless contraindicated) in combination with Nexletol or Nexlizet.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

NINLARO

Products Affected

- Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed, and treatment response. Used in combination with Revlimid (lenalidomide) and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	Must have an intolerance or contraindication to Velcade
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NOXAFIL

Products Affected

- Noxafil oral susp,delayed release for recon
- Noxafil oral suspension
- posaconazole oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, therapies tried, and outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed Infectious disease specialist, transplant specialist, hematologist, or oncologist
Coverage Duration	6 months
Other Criteria	For the treatment of aspergillosis patient must have failure of, intolerance or contraindication to vorconizole OR rationale as to why vorconizole is not suitable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUBEQA

Products Affected

- Nubeqa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to darolutamide.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or urologist.
Coverage Duration	5 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For patients with asthma: allergen test, baseline FEV1, FEV1 following bronchodilator, asthma medical history (including medications, emergency department visits, and hospitalizations), baseline eosinophil count. For patients with eosinophilic granulomatosis with polyangiitis: documentation of diagnosis, prior therapies, and the outcome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a: pulmonologist, immunologist, allergist, rheumatologist, hematologist or otolaryngologist.
Coverage Duration	3 years
Other Criteria	For patients with asthma: must be currently receiving inhaled and/or oral corticosteroid treatment, AND have a baseline eosinophil count of 300 cells/mcL or greater within previous 12 months or 150 cell/mcL within previous 6 weeks.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUEDEXTA

Products Affected

- Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by or in consultation with a neurologist, psychiatrist or geriatrician.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUPLAZID

Products Affected

- Nuplazid

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by or in consultation with a neurologist or psychiatrist
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NURTEC

Products Affected

- Nurtec ODT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a headache specialist, pain management specialist or neurologist.
Coverage Duration	1 year
Other Criteria	For acute migraine : Unless contraindicated per the FDA label, a trial of at least one-month of two different triptans: one oral tablet and one other formulation, either nasal spray or injection. For chronic migraine: Patient must have an inadequate response, contraindication, or intolerance to two different chronic migraine prevention drugs. The two prerequisite drugs must be from different classes such as anticonvulsants (topiramate/valproate), beta blockers (propranolol, metoprolol), and antidepressants (nortriptyline/venlafaxine).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCALIVA

Products Affected

- Ocaliva

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and failed, and response to therapy, baseline alkaline phosphatase (ALP) level for initiation, and ALP levels after first 3 months of therapy and then yearly for continuation of therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Use in combination with ursodiol in patients with an inadequate biochemical response to treatment (elevated ALP levels) with ursodiol dosed at 13-15 mg/kg/day for at least 1 year, may be used as monotherapy in patients unable to tolerate ursodiol. Must show improvement in ALP levels for continuation.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ODOMZO

Products Affected

- Odomzo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient has recurring disease following surgery or radiation OR patient is not a candidate for surgery or radiation therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or dermatologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OJJAARA

Products Affected

- Ojjaara

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	Diagnosis of Myelfibrosis intermediate or high-risk, primary or secondary, with anemia
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ONUREG

Products Affected

- Onureg

PA Criteria	Criteria Details
Exclusion Criteria	Do not substitute ONUREG for intravenous or subcutaneous azacitidine.
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by an oncologist or hematologist oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORENCIA

Products Affected

- Orencia ClickJect
- Orencia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other treatments tried and reasons for failure. Regular monitoring for TB required, both at baseline and during treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY A RHEUMATOLOGIST
Coverage Duration	3 year
Other Criteria	For arthritic conditions, a 3 month trial at least one non-biologic DMARD (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine) and documented reason for failure (or contraindication).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORFADIN

Products Affected

- nitisinone
- Orfadin oral suspension

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS AND WEIGHT
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY AN ENDOCRINOLOGIST, GASTROENTEROLOGIST, HEMATOLOGIST, METABOLIC SPECIALIST, OR NEPHROLOGIST
Coverage Duration	6 months
Other Criteria	CLOSE MONITORING OF DISEASE MARKERS (ERYTHROCYTE PBG-SYNTHASE ACTIVITY, URINE 5-ALA, SUCCINYLACETONE) DURING THE FIRST 3 MONTHS OF TREATMENT TO ENSURE NORMALIZATION
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORGOVYX

Products Affected

- Orgovyx

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to relugolix.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Presribing limited to oncologist or urologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORKAMBI

Products Affected

- Orkambi oral granules in packet 100-125 mg, 150-188 mg, 75-94 mg
- Orkambi oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient has a diagnosis of cystic fibrosis (CF) AND Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene AND The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second [FEV1], decreased number of pulmonary exacerbations)
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORLISSA

Products Affected

- Orilissa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Must have a failure, contraindication, or intolerance to a continuous hormonal contraceptive AND progestin therapy (e.g. medroxyprogesterone, norethindrone).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORSERDU

Products Affected

- Orserdu

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by? hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OTEZLA

Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a Rheumatologist or Dermatologist
Coverage Duration	3 year
Other Criteria	For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OXERVATE

Products Affected

- Oxervate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an ophthalmologist
Coverage Duration	8 weeks
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PALYNZIQ

Products Affected

- Palynziq

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, and outcome. Baseline and follow up phenylalanine (Phe) concentrations.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Must have phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management, and a failure, contraindication, or intolerance to Kuvan.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PANRETIN

Products Affected

- Panretin

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PDE-5 INHIBITORS FOR PAH

Products Affected

- Alyq
- sildenafil (Pulmonary Arterial Hypertension) oral suspension for reconstitution 10 mg/mL
- sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg
- tadalafil (pulmonary arterial hypertension) oral tablet 20 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results.
Age Restrictions	N/A
Prescriber Restrictions	For PAH: prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Sildenafil must be tried prior to the use of the other drugs included in these criteria, unless using ambrisentan (Letairis) plus tadalafil for treatment-naive, WHO functional class II or III PAH.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PEMAZYRE

Products Affected

- Pemazyre

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to pemigatinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by an oncologist or gastroenterologist.
Coverage Duration	5 years
Other Criteria	Documentation of a susceptible fibroblast growth factor receptor 2 fusion or other genetic rearrangement (as detected by an FDA-approved test).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PIQRAY

Products Affected

- Piqray

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, and E): A)The patient is a postmenopausal female or a male AND B)The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C)The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D)The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E)The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POMALYST

Products Affected

- Pomalyst

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PROLIA

Products Affected

- Prolia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed or in consultation with Endocrinologist, Hematologist/Oncologist, Obstetrician/Gynecologist, Rheumatologist or Urologist
Coverage Duration	3 years
Other Criteria	For treatment of postmenopausal osteoporosis / treatment of osteoporosis in men [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: (1) has had inadequate response after 6 months of therapy with an oral bisphosphonate or (2) had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate or (3) the patient cannot take an oral bisphosphonate because (s)he cannot swallow or has difficulty swallowing, cannot remain in an upright position, or has a pre-existing GI medical condition - AND - the patient has tried an IV bisphosphonate (e.g., ibandronate or zoledronic acid). Part B before Part D Step Therapy. Approve if the patient has severe chronic kidney disease (e.g., creatinine clearance less than 35 mL/min). Approve for treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer or receiving adjuvant AI therapy for breast cancer. For treatment of glucocorticoid induced osteoporosis (GIO), approve if the patient has tried one oral bisphosphonate OR patient cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing, or the patient cannot remain in an upright position post oral bisphosphonate administration, or has a pre-existing GI medical condition (e.g., esophageal lesions,

PA Criteria	Criteria Details
	esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR patient has tried zoledronic acid (Reclast), OR patient has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PROMACTA

Products Affected

- Promacta

PA Criteria	Criteria Details
Exclusion Criteria	For ITP, eltrombopag should only be used if the degree of thrombocytopenia and clinical condition increase the risk for bleeding. For chronic hepatitis C, eltrombopag should only be used if the degree of thrombocytopenia prevents initiation of or limits the ability to maintain interferon-based therapy. Eltrombopag is not indicated for the treatment of myelodysplastic syndromes.
Required Medical Information	Diagnosis, other therapies tried and outcome. Platelet count.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PULMONARY HYPERTENSION

Products Affected

- ambrisentan
- bosentan
- Opsumit
- Orenitram
- Tracleer oral tablet for suspension
- Tyvaso
- Tyvaso Institutional Start Kit
- Tyvaso Refill Kit
- Tyvaso Starter Kit
- Ventavis

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis of pulmonary arterial hypertension (WHO GROUP 1). Prior therapies used and responses to treatments.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a pulmonologist or cardiologist.
Coverage Duration	3 years
Other Criteria	PAH (WHO Group 1) diagnosis confirmed by a right heart catheterization to ensure appropriate medical assessment. For new starts in the Treatment Naive patient: must initiate treatment with dual therapy with tadalafil and ambrisentan, unless intolerant or contraindicated. For these drugs: bosentan, iloprost, macitentan, treprostnil: must show documentation of prior drug treatment. Note: patients who are already established on any therapy and clinically responsive and stable, a step-back to dual therapy is not required.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PURIXAN

Products Affected

- Purixan

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY
Age Restrictions	N/A
Prescriber Restrictions	prescriber must be a oncologist or hematologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PYRUKYND

Products Affected

- Pyrukynd

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a hemoatologist or oncologist
Coverage Duration	3 months
Other Criteria	Continuation of therapy is dependant on response to therapy. Continuation will be approved for hemoglobin increase of greater than or equal to 1.5 gm/dl from baseline and decrease of transfusion burden from baseline.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

QINLOCK

Products Affected

- Qinlock

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to ripretinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a oncologist or gastroenterologist.
Coverage Duration	5 years
Other Criteria	For initiation, documentation of prior treatment with three or more kinase inhibitors, including imatinib.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RADICAVA

Products Affected

- Radicava ORS Starter Kit Susp

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a neurologist or prescriber expertise with treating ALS
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REGRANEX

Products Affected

- Regranex

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prior use of collagenase (Santyl), unless contraindicated.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Juxtapid or Praluent.
Required Medical Information	Current LDL-C (within 30 days of request), documentation of prior statin drug(s) and/or ezetimibe previously tried including dosage and response to therapy such as adverse event history (for example muscle pain) and/or inadequate reduction of LDL-C (provide lab value).
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Approve for 3 years
Other Criteria	Hyperlipidemia with HeFH - approve if: (1) diagnosis of HeFH - AND - (2) tried ezetimibe and ONE high intensity statin (e.g., atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher, unless patient is statin intolerant defined by experiencing statin-related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin, and during both trials the symptoms resolved upon discontinuation. For hyperlipidemia with ASCVD, approve if: (1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure - AND - (2) tried ezetimibe and ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher, unless patient is statin intolerant (defined above). For HoFH, approve if: (1) has one of the following: (a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR (b) untreated LDL greater than 500 mg/dL (prior to treatment), OR (c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha or Juxtapid), OR (d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous

PA Criteria	Criteria Details
	xanthomas or xanthelasma), AND - (2) tried ezetimibe and ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). For primary hyperlipidemia with LDL of 190 or higher (not associated with ASCVD, HeFH, or HoFH), approve if tried one high-intensity statin therapy (defined above) and ezetimibe for at least 8 weeks and LDL remains 100 mg/dL or higher, unless statin intolerant (defined above). Maximally tolerated statin therapy may mean zero tolerance for those patients who cannot tolerate a statin.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RETEVMO

Products Affected

- Retevmo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to selpercatinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a oncologist, pulmonologist or endocrinologist.
Coverage Duration	5 years
Other Criteria	For initiation, documentation of the presence of a RET gene fusion (with non-small cell lung cancer or thyroid cancer) or specific RET gene mutation (medullary thyroid cancer) in tumor specimens or plasma.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVCOVI

Products Affected

- Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of adenosine deaminase (ADA) deficiency, IgA, IgM and IgG levels, CBC, and the prescence of mutations in the ADA gene at 20q13.11
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an immunologist
Coverage Duration	3 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVCOVI

Products Affected

- Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of Adenosine deaminase (ADA) deficiency, IgA, IgM, and IgG levels, CBC, and presence of mutations in the ADA gene at 20q13.11
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by immunologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVLIMID

Products Affected

- lenalidomide

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	MCL-approve if the patient meets one of the following 1) Pt has tried two prior therapies or therapeutic regimens OR 2) Pt has tried one prior therapy or therapeutic regimen and cannot take Velcade according to the prescribing physician. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen. Myelofibrosis-approve if the pt has tried one other therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REYVOW

Products Affected

- Reyvow

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for migraine prevention.
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a headache specialist, pain management specialist or neurologist.
Coverage Duration	1 year
Other Criteria	Unless contraindicated per the FDA label, a trial of at least one-month of two different triptans: one oral tablet and one other formulation, either nasal spray or injection.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REZLIDHIA

Products Affected

- Rezlidhia

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by? hematologist/oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RINVOQ

Products Affected

- Rinvoq

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to UPADACITINIB.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a gastroenterologist, rheumatologist, or dermatologist
Coverage Duration	3 year
Other Criteria	Prior to receiving treatment with Rinvoq for arthritis related conditions, the patient must have trial and failure of at least one non-biologic DMARDs, including but not limited to methotrexate, hydroxychloroquine and sulfasalazine, for at least three months or have a contraindication. For atopic dermatitis: a trial on at least one topical corticosteroid (fluticasone, fluocinonide, desonide) - and - one at least one topical immunomodulator (tacrolimus, pimecrolimus). Prior to receiving treatment with Rinvoq for an ULCERATIVE COLITIS condition, the patient must have an inadequate response or intolerance to a tumor necrosis factor blockers. Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ROZLYTREK

Products Affected

- Rozlytrek oral capsule 100 mg, 200 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to ENTRECTINIB.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist.
Coverage Duration	5 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RUBRACA

Products Affected

- Rubraca

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	OVARIAN CANCER (epithelial ovarian, fallopian tube or primary peritoneal): Diagnosis of advanced ovarian cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test. History of failure, contraindication, or intolerance to two or more chemotherapies. Maintenance Therapy-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. PROSTATE CANCER: Diagnosis of advanced metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test. History of failure, contraindication, or intolerance to androgen receptor-directed therapy and a taxane-based chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RYDAPT

Products Affected

- Rydapt

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test, used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	5 years
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SAMSCA

Products Affected

- tolvaptan oral tablet 15 mg
- tolvaptan oral tablet 30 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, patient has a serum sodium less than 125 mEq/L at baseline, OR member has less marked hyponatremia (serum sodium less than 135 mEq/L at baseline) AND is symptomatic (e.g. nausea, vomiting, headache, lethargy, confusion, and baseline LFTs).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state sucha as an endocrinologist or nephrologist.
Coverage Duration	1 month
Other Criteria	Patient must have documented failure of two other therapies (e.g. fluid restriction, furosemide, demeclocycline).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SCEMBLIX

Products Affected

- Scemblix oral tablet 20 mg, 40 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, evidence of T3151 mutation
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SENSIPAR

Products Affected

- cinacalcet oral tablet 30 mg, 60 mg, 90 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments and responses.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	3 year
Other Criteria	For secondary hyperparathyroidism associated with CKD undergoing dialysis, trial and failure with ONE phosphate binder (e.g. calcium acetate, sevelamer) - AND - ONE vitamin D analog (e.g. doxercalciferol, calcitriol, paricalcitol).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIGNIFOR

Products Affected

- Signifor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and other treatments tried and failed. Documentation: of surgery with response (if performed), or when surgery is not a treatment option.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an endocrinologist
Coverage Duration	6 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIRTURO

Products Affected

- Sirturo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed. ECG and liver function tests are required at baseline and at intervals as specified in the FDA prescribing information to monitor for potentially severe adverse events.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a infectious disease specialist
Coverage Duration	24 weeks
Other Criteria	Drug therapy must be directly observed. Use of Sirturo is reserved for MDR-TB where other treatment options cannot be used for safety or efficacy reasons.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYCLARYS

Products Affected

- Skyclarys

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis and Confirmation of diagnosis via genetic testing revealing two pathogenic mutations of the frataxin (FXN) gene. Obtain alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, B-type natriuretic peptide (BNP), and lipid parameters.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by or in consultation with a Neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYRIZI

Products Affected

- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous wearable injector 180 mg/1.2 mL (150 mg/mL), 360 mg/2.4 mL (150 mg/mL)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a gastroenterologist, dermatologist, or rheumatologist
Coverage Duration	3 years
Other Criteria	For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate. For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SPRITAM

Products Affected

- Spritam

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, therapies tried, and outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by Neurologist
Coverage Duration	5 years
Other Criteria	Rationale as to why generic levetiracetam is not suitable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SPRYCEL

Products Affected

- Sprycel

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	Must have a failure, intolerance or contraindication to imatinib.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

STELARA

Products Affected

- Stelara subcutaneous solution
- Stelara subcutaneous syringe 45 mg/0.5 mL, 90 mg/mL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy. TB test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by gastroenterologist, dermatologist or rheumatologist.
Coverage Duration	3 year
Other Criteria	For arthritis conditions, must have a trial of or contraindication to one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). For diagnosis of plaque psoriasis, must have a trial of or contraindication to cyclosporine or methotrexate. For psoriasis and psoriatic arthritis, 90 mg dosing requires demonstration of treatment failure of 45 mg for 16 weeks and patient weight greater than 100kg. For inflammatory bowel disease (CD and UC), must have trial of or contraindication to at least one non-biologic conventional therapy, including but not limited to sulfasalazine, mesalamine, azathioprine, or methotrexate.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

STIVARGA

Products Affected

- Stivarga

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to regorafenib. LFT lab test results are needed for continuation treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUNOSI

Products Affected

- Sunosi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior drug treatments and outcomes.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a pulmonologist or sleep specialist.
Coverage Duration	1 year
Other Criteria	INITIATION: 1) Demonstration that co-existing hypertension has been controlled before initiating treatment with solriamfetol. 2) A one-month trial of modafinil and armodafinil, both titrated to maximum tolerated dose.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUTENT

Products Affected

- sunitinib malate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES, AND TREATMENT RESPONSE. DOCUMENATION OF FAILURE OF IMATINIB FOR PATIENTS WITH GIST. DOCUMENTATION OF FAILURE OF VOTRIENT FOR PATIENTS WITH RENAL CELL CARCINOMA. IF NO PREVIOUS FAILURE, RATIONALE AS TO WHY PREFERRED AGENT CANNOT BE USED
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	GIST PATIENTS REQUIRE A FOLLOW-UP CT SCAN BETWEEN 8 AND 12 WEEKS.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of CF AND homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patients genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. FEV1 at baseline and continuation, baseline LFT and continuation, review for drug interactions CYP3A inducers
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a pulmonologist or doctor specializing in cystic fibrosis
Coverage Duration	5 year
Other Criteria	For renewal, Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMLIN

Products Affected

- SymlinPen 120
- SymlinPen 60

PA Criteria	Criteria Details
Exclusion Criteria	GASTROPARESIS OR USE OF DRUGS TO STIMULATE GASTROINTESTINAL MOTILITY
Required Medical Information	HBA1C AND CURRENT DIABETES MEDICATIONS
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 YEAR
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMPAZAN

Products Affected

- Sympazan oral film 10 mg, 20 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	Must have failure, intolerance, or contraindication to generic clobazam
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYNRIBO

Products Affected

- Synribo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TABRECTA

Products Affected

- Tabrecta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to capmatinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by an oncologist or pulmonologist.
Coverage Duration	5 years
Other Criteria	Documentation of a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis with appropriate testing.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a cardiologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAFINLAR

Products Affected

- Tafinlar oral capsule
- Tafinlar oral tablet for suspension

PA Criteria	Criteria Details
Exclusion Criteria	Wild-type BRAF melanoma
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. Documentation of BRAF mutation, as detected using an FDA-approved test.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAGRISSO

Products Affected

- Tagrisso

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis supported with an approved test for the detection of mutations named in FDA label found in tumor or plasma specimens. Other therapies tried and responses to treatments.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TALZENNA

Products Affected

- Talzenna

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TARCEVA

Products Affected

- erlotinib

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR THERAPIES, AND TREATMENT RESPONSE
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TARGRETIN

Products Affected

- bexarotene topical

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, response to bexarotene.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribing limited to a specialist in dermatology, hematolgy, or oncology.
Coverage Duration	5 months
Other Criteria	Documentation that the patient has refractory or persistent cutaneous T-cell lymphoma (stage IA and IB) or who has not tolerated other therapies
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TASIGNA

Products Affected

- Tasigna oral capsule 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, OTHER THERAPIES TRIED AND FAILED, RESPONSE TO TREATMENT, POTENTIAL DRUG INTERACTIONS
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST
Coverage Duration	5 years
Other Criteria	Must have a failure, intolerance or contraindication to imatinib and Sprycel.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAVALISSE

Products Affected

- Tavalisse

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried, outcome, and platelet count less than 50,000/microL for at least 3 months
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a hematologist or oncologist
Coverage Duration	1 year
Other Criteria	Patient must have a failure, contraindication, or intolerance to at least two of the following therapies: corticosteroids, IVIG, Rituxan, or Promacta. For continuation of therapy the platelet counts must be to a level sufficient to avoid clinically important bleeding.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAVNEOS

Products Affected

- Tavneos

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must written hematologist, rheumatologist, neurologist, nephrologist, and immunologist
Coverage Duration	3 years
Other Criteria	Patient must have tried and failed two of the following: azathioprine, methotrexate, mycophenolate, rituximab, or cyclophosphamide
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAVNEOS

Products Affected

- Tavneos

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a board-certified rheumatologist, nephrologist, hematologist or immunologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZORAC

Products Affected

- tazarotene topical cream
- tazarotene topical gel
- Tazorac topical cream 0.05 %

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, OTHER THERAPIES TRIED AND FAILED.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 YEAR
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZVERIK

Products Affected

- Tazverik

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to tazemetostat.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribing limited to a hematologist/oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TEGSEDI

Products Affected

- Tegsedi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR). For continuation of therapy, demonstrated positive response to therapy (improved neurologic impairment, motor function, or slowing of disease progression)
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by a geneticist or neurologist
Coverage Duration	6 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TEPMETKO

Products Affected

- Tepmetko

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to TEPOTINIB.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by an oncologist or pulmonologist.
Coverage Duration	5 years
Other Criteria	For NSCLC: confirmation of genertic alteration with biomarker testing for mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TESTOSTERONE

Products Affected

- testosterone transdermal gel
- 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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TIBSOVO

Products Affected

- Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL

Products Affected

- fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
Exclusion Criteria	NOT approved for patients who are NOT tolerant to opioid drug treatment - AND - are NOT receiving long-acting opioids
Required Medical Information	Diagnosis and prior drug treatments.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Documentation that shows prior use of two formulary short-acting opioid analgesics such as oxycodone, morphine, or hydromorphone as immediate-release (IR) tablet formulations or oral solution. Explanation of treatment failure or product intolerance must also explain why this unique method of administration is medically necessary and why a traditional short-acting oral opiate medication cannot be continued.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRELSTAR DEPOT, TRELSTAR LA

Products Affected

- Trelstar intramuscular suspension for reconstitution

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRETINOIN

Products Affected

- tretinoin topical

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRIENTINE

Products Affected

- trientine oral capsule 250 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and the outcome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatatologist.
Coverage Duration	6 months
Other Criteria	Must have a failure, contraindication, or intolerance to penicillamine.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TUKYSA

Products Affected

- Tukysa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to tucatinib.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a oncologist.
Coverage Duration	5 years
Other Criteria	For initiation, documentation of human epidermal growth factor receptor 2 (HER2) testing. Documentation of one or more prior anti-HER2-based regimens in the metastatic setting.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TURALIO

Products Affected

- Turalio oral capsule 125 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis: symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery in adults. Prior therapy used, result of prior therapy. If continuation, prior response to pexidartinib.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TYKERB

Products Affected

- lapatinib

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR AND CURRENT THERAPIES, TREATMENT RESPONSE
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TYMLOS

Products Affected

- Tymlos

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for a cumulative lifetime duration of abaloparatide and any other parathyroid hormone therapy (eg, teriparatide) of more than 2 years. Not approved for combination therapy of a PTH/PTHrP analog in combination with other osteoporosis agents.
Required Medical Information	Diagnosis, fracture history, prior therapy used and response to prior therapy. Required pretreatment testing: DXA, if not performed in the past two years: serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D), and, 24-hour urine calcium, creatinine (or fasting specimen for calcium/creatine ratio) to evaluate for baseline hypercalciuria.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an endocrinologist.
Coverage Duration	2 years
Other Criteria	Documentation of a trial on an oral bisphosphonate, or, if GI intolerant of oral bisphosphonates, use of a parenteral bisphosphonate - AND - a trial on denosumab.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UBRELVY

Products Affected

- Ubrelvy

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for migraine prevention.
Required Medical Information	N/A
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a neurologist, pain management specialist or headache specialist.
Coverage Duration	1 year
Other Criteria	Unless contraindicated per the FDA label, a trial of at least one-month of two different triptans: one oral tablet and one other formulation, either nasal spray or injection.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UCERIS

Products Affected

- budesonide oral tablet,delayed and ext.release

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for maintenance of remission or in patients with severe disease (UCDAI score = 10)
Required Medical Information	Diagnosis, other therapies tried and/or failed, including anti-inflammatory and immunosuppressant drugs
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a gastroenterology specialist
Coverage Duration	3 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPTRAVI

Products Affected

- Uptravi oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis of PAH, other therapies tried, and documentation of response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a cardiologist or pulmonologist
Coverage Duration	3 years
Other Criteria	Must have PAH WHO group 1 . Prior to receiving treatment with Uptravi, patient must have a contraindication, intolerance to, or history of taking a PDE5 inhibitor (sildenafil or Adcirca) AND an ERA (bosentan or ambrisentan)
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UREA CYCLE DISORDER

Products Affected

- Ravicti
- sodium phenylbutyrate oral powder

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VALTOCO

Products Affected

- Valtoco

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to diazepam.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribing limited to a neurologist.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VANFLYTA

Products Affected

- Vanflyta

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Under CMS Review
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	5 years
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VASCEPA

Products Affected

- icosapent ethyl oral capsule 0.5 gram, 1 gram
- Vascepa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used and result of prior therapy. For continuation, response to icosapent ethyl.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	3 year
Other Criteria	For indication of cardiovascular risk reduction with hypertriglyceridemia: must demonstrate either established cardiovascular disease OR type 2 diabetes mellitus with at least 2 additional risk factors for cardiovascular disease AND elevated triglycerides of 150 mg/dL or higher (within 30 days of request) and use of at least two statins titrated to maximally tolerated dose. Waive the statin requirement for documented statin intolerant (e.g., zero tolerance). For renewals, must demonstrate continued use of a statin (unless documented as intolerant) and efficacy of icosapent ethyl by repeat triglyceride level within 30 days. For indication of hypertriglyceridemia: must demonstrate severe elevated triglycerides greater than 500 mg/dL within 30 days of request and trial of omega-3 acid ethyl esters. For renewals, must demonstrate efficacy of icosapent ethyl by repeat triglyceride level within 30 days.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VELTASSA

Products Affected

- Veltassa

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Evidence of episodes of moderate to severe hyperkalemia (serum potassium level = 5.1 mEq/L) requiring discontinuation or dose reduction of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and/or aldosterone antagonists AND receives medication regimen that allows for practical administration of Veltassa 3 hours before or 3 hours after other oral medications
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prior use of sodium polystryrene (SPS) and sodium zirconium cyclosilicate (Lokelma).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VENCLEXTA

Products Affected

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Other treatments tried and response to therapies.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VEOZAH

Products Affected

- Veozah

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Under CMS Review
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Patients must have an inadequate response, contraindication, or intolerance to two different medications such as conjugated estrogens, Venlafaxine, gabapentin, or clonidine.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VERZENIO

Products Affected

- Verzenio

PA Criteria	Criteria Details
Exclusion Criteria	NA
Required Medical Information	Documentation of diagnosis, previous treatments, response to treatment, and LFTs.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by oncology
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VITRAKVI

Products Affected

- Vitrakvi

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIZIMPRO

Products Affected

- Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VONJO

Products Affected

- Vonjo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to treatment
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by oncology and hematology
Coverage Duration	3 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VORICONAZOLE

Products Affected

- voriconazole intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for topical use such as Foot Bath, Nasal Rinse, Mouthwash, etc. applications.
Required Medical Information	Medically accepted indication.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VOTRIENT

Products Affected

- Votrient

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, OTHER THERAPIES TRIED AND FAILED, RESPONSE TO TREATMENT
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VOXZOGO

Products Affected

- Voxzogo

PA Criteria	Criteria Details
Exclusion Criteria	limb surgery
Required Medical Information	Documentation of achondroplasia confirmed by genetic testing for variants in the fibroblast growth factor receptor 3 (FGFR3) gene, members baseline annualized growth velocity, open epiphyses AND prescriber attests that there are no plans for the member to have limb-lengthening surgery and the member has not had limb-lengthening surgery.
Age Restrictions	5 years or older
Prescriber Restrictions	Prescribed by or in consultation with a board-certified geneticist, endocrinologist, neurologist, orthopedic surgeon, or specialist with experience in treating achondroplasia.
Coverage Duration	5 year
Other Criteria	Documentation of members positive clinical response as demonstrated by improvement in annualized growth velocity, open epiphyses AND prescriber attests that there are no plans for the member to have limb-lengthening surgery.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VUITY

Products Affected

- Vuity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescription must by written by an optometrist or ophthalmologist
Coverage Duration	3 years for all medically accepted indications
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VUITY

Products Affected

- Vuity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of presbyopia , Failure of corrective eyeglasses or contact lenses to resolve the presbyopia symptoms, unless contraindicated or clinically significant adverse effects are experienced
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	1 year
Other Criteria	Member does not have glaucoma or ocular hypertension
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WAKIX

Products Affected

- Wakix

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to pitolisant.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescriber must be a neurologist or sleep specialist.
Coverage Duration	1 year
Other Criteria	For narocolepsy wiithout cateplexy: an adequate trial (at least 2 months) on one analeptic drug (i.e., modafinil or armodafinil) AND one CNS stimulant drug (i.e., amphetamine, methylphenidate or amphetamine/dextroamphetamine), unless intolerant or contraindicated.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WEILREG

Products Affected

- Welireg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XATMEP

Products Affected

- Xatmep

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior treatments, response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or rheumatologist
Coverage Duration	3 years
Other Criteria	Medical justification as to why member cannot use methotrexate tablets or injectable solution
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XCOPRI

Products Affected

- Xcopri
- Xcopri Maintenance Pack oral tablet 250mg/day(150 mg x1-100mg x1), 350 mg/day (200 mg x1-150mg x1)
- Xcopri Titration Pack

PA Criteria	Criteria Details
Exclusion Criteria	Not approved for patients with familial short QT syndrome.
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to cenobamate.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescription must be written by a neurologist.
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XDEMVY

Products Affected

- Xdemvy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For treatment of symptomatic Demodex blepharitis (DB). Symptoms defined as redness, inflammation, missing or misdirected eyelashes, itching along the eyelid base, and the presence of collarettes
Age Restrictions	Member is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Diagnosed by an ophthalmologist.
Coverage Duration	6 weeks
Other Criteria	eyelash epilation for examination by light microscopy for identification and confirmation of Demodex infestation OR collarettes that are visible on slit lamp examination.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XELJANZ

Products Affected

- Xeljanz oral solution
- Xeljanz oral tablet
- Xeljanz XR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, response to prior therapy. Documentation of negative TB test.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by a specialist appropriate to the disease state, such as a rheumatologist or gastroenterologist.
Coverage Duration	3 year , Xelzanz XR 22 mg - 16 weeks
Other Criteria	Prior to receiving treatment with Xeljanz for ARTHRITIS-RELATED conditions, the patient must have trial of, or contraindication to, at least one non-biologic DMARD (including but not limited to methotrexate, hydroxychloroquine, sulfasalazine, azathioprine). Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling. Prior to receiving treatment with Xeljanz XR 22 mg for an ULCERATIVE COLITIS condition, the patient must have an inadequate response or intolerance to tumor necrosis factor blockers (includng but not limited to adalimumab). Dose adjustments and laboratory monitoring parameters should be adhered to as specified in the FDA approved drug labeling.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, Somatuline Depot) for at least 3 months AND used in combination with SSA therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	3 years
Other Criteria	For continuation of therapy-Documentation of a positive clinical response to Xermelo therapy AND Xermelo will continue to be used in combination with SSA therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XGEVA

Products Affected

- Xgeva

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried and/or failed
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by oncologist
Coverage Duration	5 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XIFAXAN

Products Affected

- Xifaxan oral tablet 200 mg, 550 mg

PA Criteria	Criteria Details
Exclusion Criteria	Not covered for PROPHYLAXIS of traveler's diarrhea. For TREATMENT of traveler's diarrhea, not covered for diarrhea due to pathogens other than E. coli, and, not covered for diarrhea complicated by fever or blood in the stool.
Required Medical Information	Confirmation of diagnosis, other treatments tried and documentation of response to prior therapies.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months for all medically accepted indications, excepting 2 years for hepatic encephalopathy.
Other Criteria	For hepatic encephalopathy: treatment failure, intolerance, or contraindication to lactulose. For travelers diarrhea: treatment failure, intolerance, or contraindication to a fluoroquinolone (such as ciprofloxacin) and azithromycin. For IBS-D: treatment failure, intolerance, or contraindication to at least two of these drugs: loperamide, dicyclomine or diphenoxylate/atropine. For recurrent C. difficile: treatment failure, intolerance, or contraindication to vancomycin.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For asthma: weight, IgE level at baseline, baseline FEV1, FEV1 following bronchodilator, medication history, ER visits, and hospitalizations. Evidence of a positive skin test or in-vitro reactivity to a perennial aeroallergen. For uticaria: documentation of persistence of hives associated with itching and prior treatments with outcome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a pulmonologist, immunologist, allergist, dermatologist or otolaryngologist.
Coverage Duration	3 year
Other Criteria	Moderate to severe persistent asthma approve if the patient meets criteria 1 and 2: 1) patient has received combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months. For chronic idiopathic urticaria (CIU), approve if the patient has documented CIU for at

PA Criteria	Criteria Details
	least 6 weeks AND failure, intolerance, or contraindication to cyclosporine and montelukast. For continuation of asthma treatment - The patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For continuation of CIU treatment - The patient must have responded to therapy as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOSPATA

Products Affected

- Xospata

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies, and result of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XPOVIO

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	N/A
Required Medical Information	Diagnosis, other therapies tried and treatment responses.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or hematologist.
Coverage Duration	5 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XTANDI

Products Affected

- Xtandi oral capsule
- Xtandi oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy used, result of prior therapy. If continuation, prior response to enzalutamide.
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by an oncologist or urologist
Coverage Duration	5 years
Other Criteria	Patient must undergo evaluation of seizure risk. For metastatic castration resistant prostate cancer (CRPC) -- OR -- metastatic castration-sensitive prostate cancer (CSPC), patient must have a failure, intolerance, or contraindication to abiraterone (Zytiga) prior to initiation of therapy with enzalutamide (Xtandi).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XURIDEN

Products Affected

- Xuriden

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	The starting dose will be approved for 60 mg/kg once daily. Higher doses will be approved (up to 120 mg/kg once daily) in the following situations: Levels of orotic acid in urine remain above normal or increase above the usual or expected range for the patient OR Laboratory values (e.g., red blood cell or white blood cell indices) affected by hereditary orotic aciduria show evidence of worsening OR Worsening of other signs or symptoms of the disease
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XYREM

Products Affected

- sodium oxybate
- Xyrem

PA Criteria	Criteria Details
Exclusion Criteria	Not to be used in patients concurrently using alcohol or sedative-hypnotic agents
Required Medical Information	Diagnosis, other therapies tried and failed
Age Restrictions	N/A
Prescriber Restrictions	Prescription must be written by a sleep medicine specialist or neurologist
Coverage Duration	6 months
Other Criteria	Dosing approved up to 9 grams per day
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZEJULA

Products Affected

- Zejula

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, prior therapies, and response to therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZELBORAF

Products Affected

- Zelboraf

PA Criteria	Criteria Details
Exclusion Criteria	PATIENTS WITH WILD-TYPE BRAF MELANOMA, PREGNANCY
Required Medical Information	FOR METASTATIC MELANOMA: DOCUMENTATION OF DIAGONSIS AND BRAF V600E MUTATION AS DETECTED USING AN FDA-APPROVED TEST. FOR ERDHEIM-CHESTER DISEASE: DOCUMENTATION OF DIAGNOSIS AND BRAF V600 MUTATION.
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY AN ONCOLOGIST.
Coverage Duration	5 years
Other Criteria	PERFORM DERMATOLOGICAL EVALUATIONS PRIOR TO INITIATION OF THERAPY AND EVERY 2 MONTHS WHILE ON THERAPY TO MONITOR FOR NEW PRIMARY MELANOMAS. MONITOR LIVER FUNCTION TESTS PRIOR TO INITIATION OF THERAPY AND AS CLINICALLY INDICATED THEREAFTER. MONITOR ECGs PRIOR TO INITIATION OF THERAPY, AT DAY 15, THEN MONTHLY, AND EVERY 3 MONTHS THEREAFTER.MONITOR PATIENTS FOR OPHTHALMOLOGIC REACTIONS AS CLINICALLY INDICATED.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZONISADE

Products Affected

- Zonisade

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments, and response therapy
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information
Prescriber Restrictions	N/A
Coverage Duration	5 years
Other Criteria	Must have a intolerance, contraindication, or medical reason the capsule are not acceptable.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZTALMY

Products Affected

- Ztalmy

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis, previous treatments, and response to treatment.
Age Restrictions	Beneficiary is of appropriate age for use per FDA prescribing information.
Prescriber Restrictions	Prescribed by? Neurologist
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYDELIG

Products Affected

- Zydelig

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	DIAGNOSIS, PRIOR TREATMENTS, RESPONSE TO THERAPY. FOR PATIENTS WITH CLL, DOCUMENTATION OF PRIOR TREATMENT WITH IMBRUVICA. IF NO PREVIOUS FAILURE, RATIONALE AS TO WHY PREFERRED AGENT CANNOT BE USED
Age Restrictions	N/A
Prescriber Restrictions	PRESCRIPTION MUST BE WRITTEN BY ONCOLOGIST OR HEMATOLOGIST
Coverage Duration	5 years
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PART B VERSUS PART D

Products Affected

- Abelcet intravenous suspension 5 mg/mL
- acetylcysteine solution 100 mg/mL (10 %), 200 mg/mL (20 %)
- acyclovir sodium intravenous solution 50 mg/mL
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 2.5 mg/0.5 mL, 5 mg/mL
- AmBisome intravenous suspension for reconstitution 50 mg
- amphotericin B injection recon soln 50 mg
- arformoterol inhalation solution for nebulization 15 mcg/2 mL
- Azasan oral tablet 100 mg, 75 mg
- azathioprine oral tablet 100 mg, 50 mg, 75 mg
- bleomycin injection recon soln 15 unit, 30 unit
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- Clinimix 5%/D15W Sulfite Free intravenous parenteral solution 5 %
- Clinimix 4.25%/D10W Sulf Free intravenous parenteral solution 4.25 %
- Clinimix 4.25%/D5W Sulfit Free intravenous parenteral solution 4.25 %
- Clinimix 5%-D20W(sulfite-free) intravenous parenteral solution 5 %
- Clinimix E 2.75%/D5W Sulf Free intravenous parenteral solution 2.75 %
- Clinimix E 4.25%/D10W Sul Free intravenous parenteral solution 4.25 %
- Clinimix E 4.25%/D5W Sulf Free intravenous parenteral solution 4.25 %
- Clinimix E 5%/D15W Sulfit Free intravenous parenteral solution 5 %
- Clinimix E 5%/D20W Sulfit Free intravenous parenteral solution 5 %
- Clinisol SF 15 % intravenous parenteral solution 15 %
- cromolyn inhalation solution for nebulization 20 mg/2 mL
- cyclophosphamide oral capsule 25 mg, 50 mg
- cyclophosphamide oral tablet 25 mg, 50 mg
- cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg
- cyclosporine modified oral solution 100 mg/mL
- cyclosporine oral capsule 100 mg, 25 mg
- Engerix-B (PF) intramuscular suspension 20 mcg/mL
- Engerix-B (PF) intramuscular syringe 20 mcg/mL
- Engerix-B Pediatric (PF) intramuscular syringe 10 mcg/0.5 mL
- everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg
- formoterol fumarate inhalation solution for nebulization 20 mcg/2 mL
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution 100 mg/mL
- granisetron HCl oral tablet 1 mg
- Heplisav-B (PF) intramuscular syringe 20 mcg/0.5 mL
- Imovax Rabies Vaccine (PF) intramuscular recon soln 2.5 unit
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- ipratropium bromide inhalation solution 0.02 %
- ipratropium-albuterol inhalation solution for nebulization 0.5 mg-3 mg(2.5 mg base)/3 mL
- levalbuterol HCl inhalation solution for nebulization 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/0.5 mL, 1.25 mg/3 mL

- methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg
- Millipred oral tablet 5 mg
- mycophenolate mofetil oral capsule 250 mg
- mycophenolate mofetil oral suspension for reconstitution 200 mg/mL
- mycophenolate mofetil oral tablet 500 mg
- mycophenolate sodium oral tablet,delayed release (DR/EC) 180 mg, 360 mg
- ondansetron HCl oral solution 4 mg/5 mL
- ondansetron HCl oral tablet 4 mg, 8 mg
- ondansetron oral tablet,disintegrating 4 mg, 8 mg
- pentamidine inhalation recon soln 300 mg
- Plenamine intravenous parenteral solution 15 %
- prednisolone oral solution 15 mg/5 mL
- prednisolone oral tablet 5 mg
- prednisolone sodium phosphate oral solution 10 mg/5 mL, 20 mg/5 mL (4 mg/mL), 25 mg/5 mL (5 mg/mL), 5 mg base/5 mL (6.7 mg/5 mL)
- Prednisone Intensol oral concentrate 5 mg/mL
- prednisone oral solution 5 mg/5 mL
- prednisone oral tablet 1 mg, 10 mg, 2.5 mg, 20 mg, 5 mg, 50 mg
- Prehevbrio (PF) intramuscular suspension 10 mcg/mL
- Premasol 10 % intravenous parenteral solution 10 %
- Prograf oral granules in packet 0.2 mg, 1 mg
- Prosol 20 % intravenous parenteral solution
- Pulmozyme inhalation solution 1 mg/mL
- RabAvert (PF) intramuscular suspension for reconstitution 2.5 unit
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL, 5 mcg/0.5 mL
- Recombivax HB (PF) intramuscular syringe 10 mcg/mL, 5 mcg/0.5 mL
- sirolimus oral solution 1 mg/mL
- sirolimus oral tablet 0.5 mg, 1 mg, 2 mg
- tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg
- tobramycin in 0.225 % NaCl inhalation solution for nebulization 300 mg/5 mL
- tobramycin inhalation solution for nebulization 300 mg/4 mL
- Travasol 10 % intravenous parenteral solution 10 %
- TrophAmine 10 % intravenous parenteral solution 10 %
- Yupelri inhalation solution for nebulization 175 mcg/3 mL

Details

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.

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