Prior Authorization Requirements

Effective 01/01/2027

Abatacept

Products Affected

- ORENCIA (WITH MALTOSE)
- 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	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Abemaciclib - CDK 4/6

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Abiraterone - Oral Oncology

Products Affected

- *abiraterone oral tablet 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Abiraterone - Yonsa

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis as confirmed by elevated prostate-specific antigen (PSA) test and any one of the following: biopsy, imaging study or lab diagnostic test such as 4Kscore Test or Prostate Health Index (PHI). Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or urologist.
Coverage Duration	One year.
Other Criteria	Covered for a diagnosis of metastatic castration-resistant prostate cancer. In addition, documentation of contraindication to both abiraterone and Xtandi (enzalutamide) must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Abiraterone/Niraparib - Oral Oncology

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Acalabrutinib - BTKi

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Acoramidis

Products Affected

- ATTRUBY

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Adagrasib - Oral Oncology

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Adalimumab - Humira Biosims

Products Affected

- HADLIMA
- HADLIMA (CITRATE-FREE)
- HADLIMA (CITRATE-FREE) PUSHTOUCH
- HADLIMA PUSHTOUCH
- SIMLANDI (CITRATE-FREE) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Adapalene - Topical Retinoids

Products Affected

- *adapalene topical cream*
- *adapalene topical gel 0.3 %*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used for cosmetic purposes
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Approved for the diagnosis of acne vulgaris. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Afatinib - Oral Oncology

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Alectinib - Oral Oncology

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Alpelisib - Oral Oncology

Products Affected

- PIQRAY

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Alpelisib - Vijoice

Products Affected

- VIJOICE ORAL GRANULES IN PACKET
- VIJOICE ORAL TABLET 125 MG, 250 MG/DAY (200 MG X1-50 MG X1), 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Alpha 1-Antitrypsin

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Amantadine - Parkinson's

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ambrisentan - Pulmonary Arterial Hypertension (PAH)

Products Affected

- *ambrisentan oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Amifampridine

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Amikacin

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Amphetamine

Products Affected

- *amphetamine sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used for weight loss, even if non-cosmetic (such as morbid obesity).
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Anakinra

Products Affected

- KINERET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Apalutamide

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Apomorphine - Parkinson's

Products Affected

- *apomorphine*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Apremilast

Products Affected

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20 MG (51), 10 MG (4)-20 MG (4)-30 MG (47)
- OTEZLA XR
- OTEZLA XR INITIATION

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Aripiprazole - Behavioral Health

Products Affected

- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Coverage of Opipza oral film requires documentation that all other oral dosage forms of aripiprazole (oral solution, oral tablets, oral disintegrating tablets) cannot instead be used. Additionally, for the shared indications MAJOR DEPRESSIVE DISORDER (MDD) and SCHIZOPHRENIA, documentation of a contraindication, inadequate response, or intolerance to Vraylar is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Armodafinil - Sleep Disorders

Products Affected

- *armodafinil*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Asciminib - Oral Oncology

Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Asenapine - Behavioral Health

Products Affected

- *asenapine maleate*
- SECUADO

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For BIPOLAR DISORDER, coverage of asenapine requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For SCHIZOPHRENIA, coverage of asenapine or Secuado requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Avacopan

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Avapritinib - Oral Oncology

Products Affected

- AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Avatrombopag

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Avutometinib/Defactinib - Oral Oncology

Products Affected

- AVMAPKI-FAKZYNJA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Axitinib - Oral Oncology

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Azacitidine - Oral Oncology

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Belimumab

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Belumosudil

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Belzutifan

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Betamethasone/Calcipotriene - Topical Psoriasis Combos

Products Affected

- *calcipotriene-betamethasone*
- ENSTILAR

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for a diagnosis of psoriasis. In addition, there must be lack of clinical response or intolerance to one generic topical steroid AND either a generic topical vitamin D analog or a generic topical retinoid. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Bexarotene - Bexarotene Gel

Products Affected

- *bexarotene topical*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or dermatologist.
Coverage Duration	One year.
Other Criteria	Covered for a diagnosis of refractory or persistent cutaneous t-cell lymphoma (CTCL) (stage 1a or 1b) after failure with or inability to tolerate at least one other therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Binimetinib - BRAF/MEK

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Bosentan - Pulmonary Arterial Hypertension (PAH)

Products Affected

- *bosentan oral tablet 125 mg, 62.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Bosutinib - Oral Oncology

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG
- *bosutinib oral tablet 100 mg, 400 mg, 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Brensocatib

Products Affected

- BRINSUPRI

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis of non-cystic fibrosis bronchiectasis (NCFB), confirmed (or documented) by high-resolution chest CT scan.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pulmonologist or infectious disease specialist experienced in treating bronchiectasis.
Coverage Duration	One year.
Other Criteria	There must be a documented history of at least 2 pulmonary exacerbations in the past 12 months requiring systemic antibiotics OR at least 1 exacerbation requiring hospitalization/IV antibiotics.Recertification requires documentation of or provider attestation of clinical benefit (i.e., a reduction in pulmonary exacerbations, improved symptoms). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Brexpiprazole - Behavioral Health

Products Affected

- REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for AGITATION ASSOCIATED WITH DEMENTIA DUE TO ALZHEIMER DISEASE. For MAJOR DEPRESSIVE DISORDER (MDD), coverage of Rexulti requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment indicated for MDD (such as SSRIs, SNRIs, bupropion, mirtazapine). For SCHIZOPHRENIA, coverage of Rexulti requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Brigatinib - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Budesonide - Budesonide Foam

Products Affected

- *budesonide rectal*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling. As topical budesonide does not have proven efficacy to maintain remission, chronic therapy with budesonide foam will not be authorized.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a gastroenterologist
Coverage Duration	Initial approval - 6 weeks. Subsequent courses will be authorized at 6-week intervals.
Other Criteria	For the treatment of ulcerative colitis, the patient must have had a contraindication, inadequate response, or severe intolerance to/serious side effects from topical mesalamine (enemas or suppositories), or hydrocortisone enemas. Approval for future treatment courses will require documentation of remission from the initial course of therapy. In addition, documentation that remission failed on a course of an appropriate immunomodulator or biologic will be required. If the criteria are met, subsequent treatment courses will be approved in 6-week intervals. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Budesonide - Tarpeyo

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Bupropion/Dextromethorphan - Behavioral Health

Products Affected

- AUVELITY ORAL TABLET, IR AND ER, BIPHASIC
- AUVELITY ORAL TABLET,IR ER BIPHASIC,DOSEPACK

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For MAJOR DEPRESSIVE DISORDER (MDD), coverage of Auvelity requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment indicated for MDD (such as SSRIs, SNRIs, bupropion, mirtazapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

C1 Esterase Inhibitor - Prophylactic Hereditary Angioedema (HAE)

Products Affected

- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Cabozantinib - Oral Oncology

Products Affected

- CABOMETYX
- COMETRIQ

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Cannabidiol

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Capivasertib - Oral Oncology

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Caplacizumab

Products Affected

- CABLIVI INJECTION KIT

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, attestation patient will continue to receive plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab) while using Cablivi.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a hematologist
Coverage Duration	Initial approval - 3 months. Recertification - 1 month.
Other Criteria	Covered for patients with a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) when being used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab). Should documentation of underlying disease persist (such as suppressed ADAMTS13 activity levels) after the initial treatment period (up to 30 days beyond the last plasma exchange), recertification will be approved for an additional 1 month of therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Capmatinib - Oral Oncology

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Carglumic Acid

Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for acute or chronic hyperammonemia due to the deficiency of the hepatic enzyme n-acetylglutamate synthase (NAGS). Covered as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Cariprazine - Behavioral Health

Products Affected

- VRAYLAR

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For BIPOLAR DISORDER, coverage of Vraylar requires documentation of a contraindication, inadequate response, or intolerance to two generic first-line treatments (such as lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For MAJOR DEPRESSIVE DISORDER (MDD), Vraylar requires documentation of a contraindication, inadequate response, or intolerance to TWO generic first-line treatments indicated for MDD (such as SSRIs, SNRIs, bupropion, mirtazapine). For SCHIZOPHRENIA, coverage of Vraylar requires documentation of a contraindication, inadequate response, or intolerance to two generic first-line treatments (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Cedazuridine/Decitabine - Oral Oncology

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ceritinib - Oral Oncology

Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Cholic Acid

Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Chorionic Gonadotropin

Products Affected

- *chorionic gonadotropin, human intramuscular*
- PREGNYL

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used to promote fertility.
Required Medical Information	Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Clomiphene

Products Affected

- *clomiphene citrate*
- MILOPHENE

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used to promote fertility.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Cobimetinib - BRAF/MEK

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Corticotropin - Acthar

Products Affected

- ACTHAR
- ACTHAR SELFJECT
- CORTROPHIN GEL

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	For all FDA approved indications in adults, documentation of contraindication, inadequate response, or intolerance to/serious side effects (such as steroid-induced mania or sepsis) from oral or injectable corticosteroids is required. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Crizotinib - Oral Oncology

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Crofelemer

Products Affected

- MYTESI

PA Criteria	Criteria Details
Exclusion Criteria	Drug therapy will not be authorized for individuals who have a history of Ulcerative colitis, Crohn's disease, Celiac sprue, chronic pancreatitis, malabsorption, or any other GI disease associated with diarrhea.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for the symptomatic relief of noninfectious diarrhea in individuals with HIV/AIDS on anti-retroviral therapy. In addition, documentation of clinical failure to either loperamide or diphenoxylate is required. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Cyclobenzaprine - High-Risk Medications

Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Cyclosporine

Products Affected

- VERKAZIA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an ophthalmologist
Coverage Duration	One year.
Other Criteria	Covered for patients with a diagnosis of vernal keratoconjunctivitis (VKC). The patient must have had serious side effects or drug failure to an ophthalmic antihistamine with mast cell stabilizer properties (such as olopatadine, azelastine, or epinastine) OR an antihistamine eye drop in combination with a mast cell stabilizer (such as cromolyn or Alocril). In addition, the patient must have had persistent symptoms despite treatment with an ophthalmic steroid or an inability to titrate off ophthalmic steroids. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Cysteamine

Products Affected

- PROCYSBI

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to penicillamine and as limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a nephrologist, genetic or metabolic specialist
Coverage Duration	One year.
Other Criteria	Covered for a diagnosis of nephropathic cystinosis in patients who have demonstrated therapeutic failure, contraindication, or intolerance to immediate release cysteamine/Cystagon. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Dabrafenib - BRAF/MEK

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Dacomitinib - Oral Oncology

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	For cancer diagnosis, must be prescribed by an oncologist or hematologist, or urologist in the case of prostate cancer. For non-cancer diagnosis, must be prescribed by an appropriate specialist.
Coverage Duration	One year
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Renewal criteria: documentation that disease progression has not occurred.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Darolutamide - Oral Oncology

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Dasatinib - Oral Oncology

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Deflazacort

Products Affected

- *deflazacort oral suspension*
- *deflazacort oral tablet 18 mg, 30 mg, 36 mg, 6 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Denosumab - Xgeva

Products Affected

- BILPREVDA
- XTRENBO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Deutetrabenazine

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Will not be covered in combination with tetrabenazine (Xenazine).
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist or a psychiatrist
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Dextromethorphan/Quinidine

Products Affected

- *dextromethorphan-quinidine*
- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests will also be evaluated for off-label use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Dichlorphenamide

Products Affected

- *dichlorphenamide*
- ORMALVI

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist or geneticist.
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Diclofenac - Actinic Keratosis

Products Affected

- *diclofenac sodium topical gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a Dermatologist or Oncologist
Coverage Duration	One year.
Other Criteria	For the treatment of actinic keratoses, patients must have had a contraindication, inadequate response, or severe intolerance to/serious side effects from generic imiquimod 5% cream and either generic fluorouracil 5% cream or generic fluorouracil solution. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Dihydroergotamine

Products Affected

- *dihydroergotamine nasal*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Donepezil/Memantine

Products Affected

- *memantine-donepezil*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Dordaviprone - Oral Oncology

Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Doxepin - Doxepin Topical Cream

Products Affected

- *doxepin topical*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Doxepin topical cream will be covered for the treatment of short-term management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Dronabinol

Products Affected

- *dronabinol oral capsule*
- SYNDROS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Droxidopa

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Dulaglutide - GLP-1 Agonists

Products Affected

- TRULICITY

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for weight management and as limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for the treatment of type 2 diabetes mellitus. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Dupilumab

Products Affected

- DUPIXENT SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML
- DUPIXENT SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Duvelisib - Oral Oncology

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Edaravone

Products Affected

- RADICAVA ORS STARTER KIT SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Efgartigimod Alfa/Hyaluronidase

Products Affected

- VYVGART HYTRULO SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Eflornithine - Oral Oncology

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Elacestrant - Oral Oncology

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Elagolix

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for patients with severe hepatic impairment (Child-Pugh C) and as limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a gynecologist
Coverage Duration	Dyspareunia/moderate hepatic impairment: 6 mos max. Other: auth 6 mos, recert 18 mos. (24 mos max)
Other Criteria	Covered for a diagnosis of pain associated with endometriosis. In addition, the patient must have a lack of clinical response, intolerance, or contraindication to at least one prescription strength nonsteroidal anti-inflammatory drug (NSAID) used in combination with hormonal therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Elagolix/Estradiol/Norethindrone

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Elapegademase

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Must not have severe thrombocytopenia (considered to be a platelet count of below 50,000 cells/microliter).
Required Medical Information	Diagnosis confirmed by one of the following (1 or 2): 1) Absent or very low (less than 1 percent of normal) adenosine deaminase (ADA) catalytic activity in plasma, urine, or dried blood spots prior to the initiation of enzyme replacement therapy OR 2) Molecular genetic testing confirming bi-allelic mutations in the ADA gene. Documentation of elevated deoxyadenosine triphosphate (dATP) levels or total deoxyadenosine (dAdo) nucleotides in erythrocytes (red blood cells) compared to a laboratory standard. Current body weight and thrombocyte count.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by or in consultation with an immunologist, hematologist/oncologist, or a physician that specializes in the treatment of ADA-SCID.
Coverage Duration	One year
Other Criteria	Patient must not be a suitable candidate for hematopoietic cell transplantation (HCT) at the time of the request OR have already failed HCT. Recertification requires documentation of a favorable response to treatment such as one or more of the following: a. Improvement in immune status relative to baseline before treatment (total lymphocyte and B, T, and natural killer (NK) lymphocyte counts, quantitative immunoglobulin (Ig) concentration [IgG, IgA, IgM]), b. Improvement in clinical status relative to baseline before treatment (infection rate, incidence and duration of hospitalization, and performance status) c. Normalization of plasma ADA activity, erythrocyte dATP, or total dAdo nucleotide levels compared to a laboratory standard. Requests will be evaluated for Part B vs Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Elexacaftor/Ivacaftor/Tezacaftor

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coverage will be excluded in patients that lack the required genetic mutation(s) targeted by the medication.
Required Medical Information	Diagnosis, genetic test results showing at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data. Responsive mutations are those outlined in FDA labeling.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Elranatamab - Injectable Oncology

Products Affected

- ELREXFIO

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or hematologist.
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Eltrombopag

Products Affected

- *eltrombopag olamine oral powder in packet 12.5 mg, 25 mg*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*
- PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Enasidenib - Oral Oncology

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Encorafenib - BRAF/MEK

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ensartinib - Oral Oncology

Products Affected

- ENSACOVE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Entrectinib - Oral Oncology

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Enzalutamide - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Epoetin Alfa - ESRD

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Erdafitinib - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Erenumab - CGRP Antagonists

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

ESRD - Calcium Acetate

Products Affected

- *calcium acetate(phosphat bind)*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ESRD - Lanthanum Carbonate

Products Affected

- *lanthanum*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ESRD - Sevelamer

Products Affected

- *sevelamer carbonate*
- *sevelamer hcl*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ESRD - Sucroferric Oxyhydroxide

Products Affected

- VELPHORO

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For a diagnosis of end stage renal disease on dialysis, CMS expects that this drug should routinely be provided by a dialysis center and billed to Medicare Part B as part of a bundled payment arrangement (if applicable). All other diagnoses unrelated to end stage renal disease on dialysis would be evaluated for coverage under the Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Etanercept

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an appropriate specialist to treat the stated diagnosis.
Coverage Duration	One year.
Other Criteria	For all shared indications, patient must try ONE formulary adalimumab biosimilar (Hadlima or Simlandi) before approval of Enbrel. If contraindication to Hadlima AND Simlandi, then a trial with one of these is not required before approval of Enbrel. Enbrel will also be approved for patients with documented inadequate response after a trial with any previous adalimumab product. Enbrel is covered without additional step through formulary adalimumabs for all FDA approved indications of Enbrel not shared by Hadlima and Simlandi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Etrasimod

Products Affected

- VELSIPITY

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by or in consultation with a Gastroenterologist.
Coverage Duration	One year.
Other Criteria	Covered for the treatment of moderately to severely active Ulcerative Colitis in patients who have failed to have an adequate response to or had an intolerance to two American Gastroenterological Association (AGA) higher efficacy agents such as Rinvoq and Skyrizi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Everolimus - Oral Oncology

Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet for suspension 2 mg, 3 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Fecal Microbiota Spores, Live

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Must have a stool test positive for toxigenic Clostridioides difficile within the past 30 days.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by or in consultation with a gastroenterologist or infectious diseases specialist.
Coverage Duration	One month.
Other Criteria	Covered for prevention of Clostridioides difficile infection (CDI) in patients who have had at least 2 recurrent episodes of CDI. Must have completed an antibiotic course for the treatment of CDI two to four days before initiation of treatment with Vowst. Patient must not be immune compromised. Retreatment with Vowst for the same CDI will not be covered. Vowst will not be covered for the treatment of active CDI. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Fedratinib - Oral Oncology

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Fenfluramine

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist
Coverage Duration	One year
Other Criteria	Covered for patients with a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Finerenone

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for chronic kidney disease associated with type 2 diabetes in patients with inadequate response, intolerance, or contraindication to an ACE-I or ARB. Covered for heart failure with left ventricular ejection fraction greater than or equal to 40% in patients with inadequate response, intolerance, or contraindication to an ACE-I or ARB AND an SGLT2.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Fruquintinib - Oral Oncology

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Futibatinib - Oral Oncology

Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Gabapentin - Gabapentin ER

Products Affected

- *gabapentin oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	For the treatment of post-herpetic neuralgia, there must be documentation of intolerance or contraindication to generic immediate-release gabapentin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Ganaxolone

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Gefitinib - Oral Oncology

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Gepirone - Behavioral Health

Products Affected

- EXXUA ORAL TABLET EXTENDED RELEASE 24 HR
- EXXUA ORAL TABLET, EXT REL 24HR DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Gilteritinib - Oral Oncology

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Glasdegib - Oral Oncology

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Glecaprevir/Pibrentasvir

Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Glutamine

Products Affected

- *glutamine (sickle cell)*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a hematologist
Coverage Duration	One year.
Other Criteria	Covered for reducing the acute complications of sickle cell disease, including symptomatic pain relief. Patient must have experienced inadequate pain relief with a minimum three-month trial or a hematologic toxicity reaction with hydroxyurea monotherapy. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Halobetasol/Tazarotene - Topical Psoriasis Combos

Products Affected

- DUOBRII

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for a diagnosis of psoriasis. In addition, there must be lack of clinical response or intolerance to one generic topical steroid AND either a generic topical vitamin D analog or a generic topical retinoid. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Iberdomide - Oral Oncology

Products Affected

- ZENBEXUS

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	For cancer diagnosis, must be prescribed by an oncologist or hematologist, or urologist in the case of prostate cancer. For non-cancer diagnosis, must be prescribed by an appropriate specialist.
Coverage Duration	One year
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Renewal criteria: documentation that disease progression has not occurred.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Ibrutinib - BTKi

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Icatibant - Acute HAE

Products Affected

- *icatibant*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for the prophylaxis of hereditary angioedema attacks.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by allergist, immunologist, hematologist, or dermatologist
Coverage Duration	One year
Other Criteria	Covered for a confirmed diagnosis of HAE Type 1, Type II, or Type III for the treatment of acute hereditary angioedema attacks. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Idelalisib - Oral Oncology

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	For cancer diagnosis, must be prescribed by an oncologist or hematologist, or urologist in the case of prostate cancer. For non-cancer diagnosis, must be prescribed by an appropriate specialist.
Coverage Duration	One year
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Renewal criteria: documentation that disease progression has not occurred.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Iloperidone - Behavioral Health

Products Affected

- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B
- FANAPT TITRATION PACK C

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For BIPOLAR DISORDER, coverage of Fanapt requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). For SCHIZOPHRENIA, coverage of Fanapt requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Imatinib - Oral Oncology

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*
- IMKELDI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Imlunestrant - Oral Oncology

Products Affected

- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Immunoglobulin G - IVIG

Products Affected

- GAMMAGARD LIQUID
- GAMMAGARD LIQUID ERC
- GAMMAKED
- GAMUNEX-C
- OCTAGAM
- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	Excluded under Part D if intravenous immune globulin (IVIG) is provided in the home for individual with diagnosis of primary immune deficiency disease.
Required Medical Information	Diagnosis, including supporting labs/diagnostic test results. For immune thrombocytopenic purpura (ITP), submission of platelet count with the requirement with a requirement it is less than 30,000/mcL or less than 50,000/mcL with documented increased risk of bleeding.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	Two years for chronic conditions. One month for acute conditions. 5 days for Guillain-Barre
Other Criteria	Requests will be evaluated for Part B vs Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Immunoglobulin G - SCIG

Products Affected

- HIZENTRA
- HYQVIA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	Two years for chronic conditions. One month for acute conditions. 5 days for Guillain-Barre.
Other Criteria	Requests will be evaluated for Part B vs Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Inavolisib - Oral Oncology

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Infliximab

Products Affected

- ZYMFENTRA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by or in consultation with a Gastroenterologist.
Coverage Duration	One year.
Other Criteria	Covered for the treatment of moderately to severely active Crohn's Disease in patients with a documented failure of two American Gastroenterological Association (AGA) higher efficacy agents: Hadlima, Rinvoq, Selarsdi, Simlandi, Skyrizi, Yesintek. Covered for the treatment of moderately to severely active Ulcerative Colitis (UC) in patients who have failed to have an adequate response to or had an intolerance to two AGA higher efficacy agents such as Rinvoq and Skyrizi. For those already established on maintenance IV infliximab, no prerequisite is required. DOSING for CD and UC: Approved for 120mg every 2 weeks as maintenance therapy after IV induction. For CD: Dose escalation to 120mg weekly or 240mg every 2 weeks (4ml per 28 days) will be approved if converting from high-dose IV maintenance therapy (eg, 10 mg/kg IV every 4 weeks) or in patients who experience breakthrough symptoms on lower SUBQ maintenance doses. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Interferon Gamma-1B

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Istradefylline - Parkinson's

Products Affected

- NOURIANZ

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	One year
Other Criteria	For the treatment of off episodes in Parkinson's disease Nourianz is covered for patients who have documentation of a contraindication, inadequate response, or intolerance to TWO generic anti-Parkinson's disease drugs with different mechanisms of action. Examples include COMT inhibitors (entacapone and tolcapone), dopamine agonists (pramipexole, ropinirole, amantadine, and bromocriptine), MAO B-inhibitors (rasagiline and selegiline), and anticholinergics (benztropine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Ivacaftor

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ivacaftor/Lumacaftor

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Coverage will be excluded in patients with Cystic Fibrosis who are not homozygous for the F508del mutation in the CFTR gene.
Required Medical Information	Documentation of diagnosis, pertinent lab/diagnostic results to include testing that shows two copies of the F508 del mutation in the conductance regulator (CFTR) gene.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Ivacaftor/Tezacaftor

Products Affected

- SYMDEKO ORAL TABLETS, SEQUENTIAL 100-150 MG (D)/ 150 MG (N), 50-75 MG (D)/ 75 MG (N)

PA Criteria	Criteria Details
Exclusion Criteria	Coverage will be excluded in patients that lack the required genetic mutation(s) targeted by the medication.
Required Medical Information	Documentation of diagnosis, pertinent lab/diagnostic results to include testing that shows either two copies of the F508 del mutation in the conductance regulator (CFTR) gene or at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor (Symdeko). Responsive mutations are those outlined in FDA labeling.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Ivosidenib - Oral Oncology

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ixazomib - Oral Oncology

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ketoconazole

Products Affected

- RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lacosamide

Products Affected

- MOTPOLY XR ORAL CAPSULE,EXTENDED RELEASE 24HR 100 MG, 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for a diagnosis of partial-onset seizures and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients weighing at least 50 kg. In addition, there must be documentation of severe intolerance, contraindication to or the inability to take immediate release lacosamide. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Lanadelumab - Prophylactic Hereditary Angioedema (HAE)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lapatinib - Oral Oncology

Products Affected

- *lapatinib*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Larotrectinib - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lazertinib - Oral Oncology

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lecanemab

Products Affected

- LEQEMBI IQLIK SUBCUTANEOUS AUTO-INJECTOR 360 MG/1.8 ML, 500 MG/2.5 ML (250MG/1.25MLX2)

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lenalidomide - Oral Oncology

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lenvatinib - Oral Oncology

Products Affected

- LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Leuprolide - Gonadotropin Releasing Hormone Analogs

Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Levodopa - Parkinson's

Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	One year
Other Criteria	For the treatment of off episodes in Parkinson's disease Inbrija is covered for patients who have documentation of a contraindication, inadequate response, or intolerance to TWO generic anti-Parkinson's disease drugs with different mechanisms of action. Examples include COMT inhibitors (entacapone and tolcapone), dopamine agonists (pramipexole, ropinirole, amantadine, and bromocriptine), MAO B-inhibitors (rasagiline and selegiline), and anticholinergics (benztropine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Lidocaine - Lidocaine Patch

Products Affected

- *lidocaine topical adhesive patch,medicated 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Lorlatinib - Oral Oncology

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lotilaner

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Lumateperone - Behavioral Health

Products Affected

- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Macitentan - Pulmonary Arterial Hypertension (PAH)

Products Affected

- *macitentan*
- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis, right heart catheterization results if PAH
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist
Coverage Duration	One year
Other Criteria	Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, Opsumit requires a trial with a generic ERA (ambrisentan, bosentan).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Macitentan/Tadalafil - Pulmonary Arterial Hypertension (PAH)

Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis, right heart catheterization results if PAH
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist
Coverage Duration	One year
Other Criteria	Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, Opsynvi requires a trial with a generic ERA (ambrisentan, bosentan).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Maralixibat

Products Affected

- LIVMARLI ORAL SOLUTION
- LIVMARLI ORAL TABLET 10 MG, 15 MG, 20 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Mecasermin

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Mechlorethamine

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Methamphetamine

Products Affected

- *methamphetamine*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used for weight loss, even if non-cosmetic (such as morbid obesity).
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Methylnaltrexone - Opioid-Induced Constipation

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for the treatment of opioid-induced constipation with documented lack of response or severe intolerance to generic lubiprostone or Movantik. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Metreleptin

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	Use of Myalept is excluded for the following conditions: metabolic disease not associated with congenital leptin deficiency, HIV-associated lipodystrophy
Required Medical Information	Diagnosis, including supporting labs/diagnostic test results.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for the treatment of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. Diagnosis is confirmed through low serum leptin levels and the absence of subcutaneous fat.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Midostaurin - Oral Oncology

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Mifepristone - Korlym

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Mirdametinib - Oral Oncology

Products Affected

- GOMEKLI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Mitapivat

Products Affected

- PYRUKYND ORAL TABLET 20 MG, 5 MG, 5 MG (4-WEEK PACK), 50 MG
- PYRUKYND ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Modafinil - Sleep Disorders

Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Momelotinib - Oral Oncology

Products Affected

- OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Neratinib - Oral Oncology

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Nilotinib - Oral Oncology

Products Affected

- CAVHANZA
- *nilotinib hcl*
- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Nintedanib

Products Affected

- *nintedanib*
- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Niraparib - Oral Oncology

Products Affected

- ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Nirogacestat - Oral Oncology

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Nitisinone

Products Affected

- HARLIKU
- *nitisinone*
- NITYR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Odevixibat

Products Affected

- BYLVAY

PA Criteria	Criteria Details
Exclusion Criteria	Clinical evidence of decompensated cirrhosis and as limited by FDA labeling.
Required Medical Information	Diagnosis of Alagille syndrome or PFIC confirmed by genetic testing, objective and/or subjective provider assessment of baseline pruritus severity.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a hepatologist, gastroenterologist, or physician knowledgeable in the management of progressive familial intrahepatic cholestasis (PFIC).
Coverage Duration	Initial approval - 6 months. Recertifications - 1 year.
Other Criteria	Covered for the treatment of cholestatic pruritus in patients at least 12 months of age who have Alagille syndrome with confirmed mutations in the JAG1 or NOTCH2 gene. Covered for treatment of pruritus due to progressive familial intrahepatic cholestasis (PFIC). Recertification for both indications requires documentation that the patient is tolerating therapy and is experiencing a decrease in pruritus from baseline based on objective and/or subjective assessment from provider. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Olanzapine/Samidorphan

Products Affected

- LYBALVI ORAL TABLET 10-10 MG, 15-10 MG, 20-10 MG, 5-10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for patients using opioids or undergoing acute opioid withdrawal.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist or psychiatrist.
Coverage Duration	One year.
Other Criteria	Coverage requires documentation of one of the following: (1) at least a 4-week trial with generic olanzapine that yielded beneficial stable clinical response but unacceptable weight gain (unacceptability as determined by provider with attribution to side effect of olanzapine), or (2) significant intolerance or therapeutic failure of two generic first-line treatments (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Olaparib - Oral Oncology

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Olutasidenib - Oral Oncology

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Omalizumab

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Omaveloxolone

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Onabotulinumtoxina - Botox

Products Affected

- BOTOX

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling. Excluded for cosmetic uses.
Required Medical Information	Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests will be evaluated for Part B vs Part D coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Osilodrostat

Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Osimertinib - Oral Oncology

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Oteseconazole

Products Affected

- VIVJOA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Oxybate - Sodium Oxybate

Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pacritinib - Oral Oncology

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Palbociclib - CDK 4/6

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pasireotide

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pazopanib - Oral Oncology

Products Affected

- *pazopanib oral tablet 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pegvisomant - Acromegaly Therapy

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pemigatinib - Oral Oncology

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pertuzumab/Trastuzumab/Hyaluronidase - Injectable Oncology

Products Affected

- PHESGO

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or hematologist.
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Pexidartinib - Oral Oncology

Products Affected

- TURALIO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pimavanserin

Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	Per the black box warning on Nuplazid, elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Therefore, Nuplazid will not be covered for elderly patients with dementia-related psychosis.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a neurologist, psychiatrist, or geriatrician
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Pirfenidone - Esbriet

Products Affected

- *pirfenidone oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pirtobrutinib - BTKi

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Plozasiran

Products Affected

- REDEMPLO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pomalidomide - Oral Oncology

Products Affected

- *pomalidomide*
- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ponatinib - Oral Oncology

Products Affected

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Pralsetinib - Oral Oncology

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Quinine

Products Affected

- *quinine sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for the treatment of leg cramps.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	Quinine sulfate is covered for the treatment of malaria infections.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Quizartinib - Oral Oncology

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Regorafenib - Oral Oncology

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Relacorilant - Oral Oncology

Products Affected

- LIFYORLI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Relugolix

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist, hematologist or for prostate cancer, a urologist.
Coverage Duration	One year.
Other Criteria	Orgovyx will be covered for patients with advanced Prostate Cancer who have a contraindication (such as high risk for cardiovascular [CV] events or a history of CV events) or had serious side effects to two of the following: degarelix (Firmagon), leuprolide (Lupron/Eligard), or triptorelin/Trelstar. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Repotrectinib - Oral Oncology

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Resmetiron

Products Affected

- REZDIFFRA ORAL TABLET 100 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Revumenib - Oral Oncology

Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ribociclib - CDK 4/6

Products Affected

- KISQALI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Rilonacept

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Rimegepant

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Riociguat - Pulmonary Arterial Hypertension (PAH)

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis, right heart catheterization results if PAH
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist
Coverage Duration	One year
Other Criteria	Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, coverage of Adempas for PAH requires trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan). Adempas is also covered for chronic thromboembolic pulmonary hypertension (CTEPH).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Ripretinib - Oral Oncology

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Risankizumab

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR MG/2.4 ML (150 MG/ML)
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 55 MG/0.37 ML
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Risdiplam

Products Affected

- EVRYSDI ORAL RECON SOLN
- EVRYSDI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Romosozumab

Products Affected

- EVENITY

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ropeginterferon Alfa-2B

Products Affected

- BESREMI
- BESREMI PEN

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling. If patient is currently taking hydroxyurea, they must transition off by gradual taper and discontinue by week 13.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or hematologist.
Coverage Duration	One year
Other Criteria	Covered for patients with a diagnosis of polycythemia vera (PV). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Rucaparib - Oral Oncology

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ruxolitinib - Opzelura

Products Affected

- OPZELURA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ruxolitinib - Oral Oncology

Products Affected

- JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sapropterin

Products Affected

- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, baseline serum phenylalanine level, current/recent phenylalanine level with each recertification
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	Initial approval - 2 months. Recertifications - 1 year.
Other Criteria	Covered as adjunct therapy for patients diagnosed with phenylketonuria (PKU). Initial approval will be for 2 months. Phenylalanine (PHE) levels should be checked one week after initiation of therapy. If PHE levels do not decrease from baseline on a 10mg/kg/day dose, the dose may be increased to 20mg/kg/day. If PHE levels do not decrease from baseline after 2 months, the patient is considered a non-responder and further therapy will not be authorized.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Sarilumab

Products Affected

- KEVZARA SUBCUTANEOUS PEN INJECTOR
- KEVZARA SUBCUTANEOUS SYRINGE 200 MG/1.14 ML

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a rheumatologist
Coverage Duration	One year.
Other Criteria	Covered for the diagnosis of moderate to severe RHEUMATOID ARTHRITIS in patients with documented failure to TWO of the following alternatives: Hadlima, Orencia, Rinvoq, Simlandi, Xeljanz/XR. Covered for the diagnosis of POLYMYALGIA RHEUMATICA (PMR) in patients who have had an inadequate response to corticosteroids or who cannot tolerate a corticosteroid taper. Covered for the diagnosis of active POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA) in patients with documented failure to TWO of the following: : Hadlima, Orencia, Rinvoq, Simlandi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Satralizumab

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Secukinumab

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Selexipag - Pulmonary Arterial Hypertension (PAH)

Products Affected

- UPTRAVI ORAL TABLET 1,000 MCG, 1,200 MCG, 1,400 MCG, 1,600 MCG, 100 MCG, 150 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis, right heart catheterization results if PAH
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist
Coverage Duration	One year
Other Criteria	Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, coverage of Uptravi for PAH requires trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Selinexor - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Selpercatinib - Oral Oncology

Products Affected

- RETEVMO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Selumetinib - Oral Oncology

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Semaglutide - GLP-1 Agonists

Products Affected

- OZEMPIC ORAL
- OZEMPIC SUBCUTANEOUS
- RYBELSUS

PA Criteria	Criteria Details
Exclusion Criteria	Excluded for weight management and as limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for the treatment of type 2 diabetes mellitus. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Semaglutide - Wegovy

Products Affected

- WEGOVY ORAL
- WEGOVY SUBCUTANEOUS PEN INJECTOR 0.25 MG/0.5 ML, 0.5 MG/0.5 ML, 1 MG/0.5 ML, 1.7 MG/0.75 ML, 2.4 MG/0.75 ML

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sevabertinib - Oral Oncology

Products Affected

- HYRNUO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sildenafil - Pulmonary Arterial Hypertension (PAH)

Products Affected

- *sildenafil (pulmonary hypertension) oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sofosbuvir - Velpatasvir - Voxilaprevir

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Solriamfetol - Sleep Disorders

Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Somatropin - Growth Hormone

Products Affected

- OMNITROPE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sonidegib - Oral Oncology

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sorafenib - Oral Oncology

Products Affected

- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sotatercept - Pulmonary Arterial Hypertension (PAH)

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sotorasib - Oral Oncology

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sparsentan

Products Affected

- FILSPARI ORAL TABLET 200 MG, 400 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Sunitinib - Oral Oncology

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Suzetrigine

Products Affected

- JOURNAVX

PA Criteria	Criteria Details
Exclusion Criteria	Will not be covered for treatment of chronic pain (defined as pain lasting one month duration or greater).
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	14 days
Other Criteria	Covered for patients with a diagnosis of moderate to severe acute pain. Acute pain is classified as pain less than one month duration and is usually sudden, time-limited, and caused by injury, trauma, or treatments such as surgery. Subsequent reviews must be for a new moderate to severe acute pain or injury. Repeat treatment for the same injury or acute pain condition will not be authorized. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Tadalafil - Pulmonary Arterial Hypertension (PAH)

Products Affected

- *tadalafil (pulmonary hypertension)*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tadalafil - Tadalafil For Daily Use

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg (generic for cialis)*

PA Criteria	Criteria Details
Exclusion Criteria	Tadalafil for daily use is excluded for the independent diagnosis of Erectile Dysfunction.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Covered for a diagnosis of benign prostatic hyperplasia (BPH).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Tafamidis - Vyndamax

Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Talazoparib - Oral Oncology

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Taletrectinib - Oral Oncology

Products Affected

- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tasimelteon - Sleep

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tavaborole - Onychomycosis

Products Affected

- *tavaborole*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tazarotene - Topical Retinoids

Products Affected

- ARAZLO
- *tazarotene*
- TRILITAS

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used for cosmetic purposes
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Approved for the diagnosis of acne vulgaris and for the diagnosis of plaque psoriasis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Tedizolid

Products Affected

- SIVEXTRO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Teduglutide

Products Affected

- GATTEX 30-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis and evidence of dependency on parenteral nutrition support.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Telotristat Ethyl

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	For the treatment of carcinoid syndrome diarrhea, coverage will not be provided in the absence of concurrent somastatin analog therapy (lanreotide or octreotide).
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist, hematologist, endocrinologist, or gastroenterologist.
Coverage Duration	One year.
Other Criteria	Covered for the treatment of carcinoid syndrome diarrhea with documentation of continued diarrhea despite a minimum 3-month trial of somastatin analog therapy (lanreotide or octreotide). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Tepotinib - Oral Oncology

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Teriparatide - Osteoporosis

Products Affected

- *teriparatide 560 mcg/2.24 ml pen*
- *teriparatide subcutaneous pen injector 20 mcg/dose (560mcg/2.24ml)*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tetrabenazine

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Thalidomide

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Tiotropium - Spiriva Respimat

Products Affected

- SPIRIVA RESPIMAT

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None.
Coverage Duration	One year.
Other Criteria	Covered for a diagnosis of CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) in patients who have had an inadequate response or contraindication to both Incruse Ellipta and Spiriva Handihaler. Covered for a diagnosis of MODERATE TO SEVERE ASTHMA as add-on maintenance therapy. Patient must have had drug failure (inadequate or poor asthma symptom control) with at least 3 months of optimal maintenance therapy. Maintenance therapy is defined as an inhaled steroid in combination with a long-acting beta agonist (ICS-LABA) or ICS in combination with a leukotriene inhibitor or theophylline. Recertification for asthma requires documentation of continued use of ICS-LABA (or other maintenance therapy) and clinical benefit from Spiriva Respimat use (such as reduced asthma exacerbations, less use of rescue inhaler). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Tipiracil/Trifluridine - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tivozanib - Oral Oncology

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tocilizumab - Actemra Biosims

Products Affected

- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an appropriate specialist to treat the stated diagnosis.
Coverage Duration	One year.
Other Criteria	Covered for all FDA approved and medically accepted indications with documented inadequate response to ONE preferred product (such as Hadlima, Simlandi, or Rinvoq). Trialed preferred product must share the FDA or medically accepted indication for which current drug is being requested. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Tofacitinib

Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an appropriate specialist to treat the stated diagnosis.
Coverage Duration	One year.
Other Criteria	Covered for ANKYLOSING SPONDYLITIS (AS) in pts who have had serious side effects or drug failure w/ ONE of: Hadlima or Simlandi. TNF-blocker-experienced pts must have had serious side effects or drug failure with any AS-indicated TNF-blocker. Covered for POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS in pts who have had inadequate response or intolerance to methotrexate (MTX) or another disease-modifying anti-rheumatic drug (DMARD) and documented failure w/ ONE of: Hadlima or Simlandi. Covered for PSORIATIC ARTHRITIS (PsA) in patients aged 2 and up. Adult patients also must have had serious side effects or drug failure with ONE of: Hadlima or Simlandi. TNF-blocker-experienced pts must have had serious side effects or drug failure with any PsA-indicated TNF-blocker. Covered for active moderate to severe RHEUMATOID ARTHRITIS (RA) in pts who have failed to respond to or are intolerant of ONE of: Hadlima or Simlandi. TNF-blocker-experienced patients must have had serious side effects or drug failure with any RA-indicated TNF-blocker. Covered for moderately to severely active ULCERATIVE COLITIS (UC) in patients who have had inadequate response or intolerance with at least ONE TNF-blocker. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

Tolvaptan - Jynarque

Products Affected

- *tolvaptan (polycys kidney dis) oral tablet 15 mg, 30 mg*
- *tolvaptan (polycys kidney dis) oral tablets, sequential 15 mg (am)/ 15 mg (pm), 30 mg (am)/ 15 mg (pm), 45 mg (am)/ 15 mg (pm), 60 mg (am)/ 30 mg (pm), 90 mg (am)/ 30 mg (pm)*

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Tolvaptan - Samsca

Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Tovorafenib - Oral Oncology

Products Affected

- OJEMDA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Trametinib - BRAF/MEK

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Treprostinil - Pulmonary Arterial Hypertension (PAH)

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- YUTREPIA

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis, right heart catheterization results if PAH
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist
Coverage Duration	One year
Other Criteria	Required for all drugs for pulmonary arterial hypertension (PAH) indication: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest. Additionally, coverage of Orenitram and Yutrepia for PAH require trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Treprostinil - Tyvaso Nebulized Inhalation

Products Affected

- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. For PAH and PAH-ILD: right heart catheterization showing a mean artery pressure of greater than or equal to 25 mmHg at rest, pulmonary capillary wedge pressure less than or equal to 15 mmHg at rest and Pulmonary Vascular Resistance (PVR) greater than 2 wood units (WU). For PAH-ILD, also require baseline PFT results confirming moderate to severely impaired lung disease including FVC less than 70%, AND high-resolution CT scan finding characteristic airway and/or parenchymal abnormalities associated with interstitial lung disease AND baseline 6-minute walk test to assess disease severity and clinical response to treatment, AND baseline NT-proBNP [N-terminal proB-type natriuretic peptide] level.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a pulmonologist or cardiologist.
Coverage Duration	One year.
Other Criteria	For PULMONARY ARTERIAL HYPERTENSION (PAH): coverage of Tyvaso inhalation solution requires a trial with a generic formulary phosphodiesterase-5 enzyme inhibitor (PDE5i) (sildenafil, tadalafil) AND a generic formulary endothelin receptor antagonist (ERA) (ambrisentan, bosentan). Recertification requires objective and/or subjective clinical evidence of disease improvement attributed to use of approved drug(s). Also covered for the treatment of PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (WHO Group 3) to improve exercise ability. Must have clinical symptoms associated with PH-ILD such as shortness of breath with exertion that is not fully explained by the severity of lung disease, decreased exercise capacity, labored breathing, fatigue, lethargy. Recertification will require documentation of stabilization or improvement in 6MWT from baseline, decrease in NT-proBNP levels as well as stabilization or reduction in disease severity such as improvements in FVC, reduction in exacerbations of the underling lung disease and clinical worsening. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Nebulized products will also be evaluated for part B versus part D coverage.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Tretinoin - Topical Retinoids

Products Affected

- ALTRENO
- *tretinoin*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded when used for cosmetic purposes
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Approved for the diagnosis of acne vulgaris. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Trientine

Products Affected

- CUVRIOR

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for patients with a diagnosis of stable Wilson's disease who are de-coppered and tolerant to penicillamine. Must have contraindication to penicillamine tablets (generic for Depen) and contraindication to trientine capsules (generic for Syprine). Recertification requires evidence of provider re-evaluation showing that patient cannot be transitioned to maintenance on penicillamine tablets (generic for Depen) or trientine capsules (generic for Syprine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Triheptanoin

Products Affected

- DOJOLVI

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis, via appropriate molecular genetic testing confirming at least one known LC-FAOD mutation such as CPT1A, CPT2, ACADVL, HADHA, or HADHB. If molecular genetic testing is not definitive, then biochemical analysis showing diminished enzyme activity measured on skin fibroblasts must be provided. In addition to one of the above, plasma or dried blood spot acylcarnitine analysis showing a characteristic pattern consistent with LC-FAOD must be provided.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by a metabolic disease specialist knowledgeable in disease-related dietary management.
Coverage Duration	One year.
Other Criteria	Covered for patients with molecularly confirmed long-chain fatty acid oxidation disorders. The use of any other medium-chain-triglyceride (MCT) product should be discontinued before starting Dojolvi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Triptorelin - Gonadotropin Releasing Hormone Analogs

Products Affected

- TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	Trelstar is covered for palliative treatment of advanced prostate cancer. Requests will also be evaluated for off-label use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Trospium/Xanomeline - Behavioral Health

Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year
Other Criteria	For SCHIZOPHRENIA, coverage of Cobenfy requires documentation of a contraindication, inadequate response, or intolerance to Vraylar and at least ONE other generic first-line treatment (such as lurasidone, lithium, valproate, aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Tucatinib - Oral Oncology

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Upadacitinib

Products Affected

- RINVOQ LQ
- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Ursodeoxycholate

Products Affected

- *ursodiol oral capsule 200 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	None
Coverage Duration	One year.
Other Criteria	Covered for the treatment of radiolucent, non-calcified gallstones in patients for whom elective cholecystectomy is medically inappropriate, as attested by provider. Covered for the prevention of gallstones in obese patients experiencing rapid weight loss. For all indications, documentation of contraindication to generic ursodiol 300 mg capsules and generic ursodiol tablets is required before the approval of ursodiol 200 mg and 400 mg capsules. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Ustekinumab - Stelara Biosims

Products Affected

- SELARSDI SUBCUTANEOUS SOLUTION MG/0.5 ML, 90 MG/ML
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vandetanib - Oral Oncology

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vedolizumab

Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis. Current and previous therapies used for the treatment of the stated diagnosis.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by or in consultation with a Gastroenterologist.
Coverage Duration	One year.
Other Criteria	Covered for the treatment of moderately to severely active Crohn's Disease in patients with a documented failure of two American Gastroenterological Association (AGA) higher efficacy agents: Hadlima, Rinvoq, Selarsdi, Simlandi, Skyrizi, Yesintek. Covered for the treatment of moderately to severely active Ulcerative Colitis in patients who have failed to have an adequate response to or had an intolerance to two AGA higher efficacy agents such as Rinvoq and Skyrizi. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Vemurafenib - BRAF/MEK

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Venetoclax - Oral Oncology

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vepdegestrant

Products Affected

- VEPPANU ORAL TABLET 100 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling.
Required Medical Information	Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an oncologist or hematologist.
Coverage Duration	One year.
Other Criteria	Covered for patients that has all 3: (1) a diagnosis of estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-), ESR1 mutated recurrent unresectable or metastatic breast cancer (mBC) AND (2) has progressed following standard first-line therapy with at least one line of endocrine therapy and a CDK 4/6 inhibitor in the metastatic setting AND (3) hasn't progressed on treatment with another selective estrogen receptor degrader (SERD).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Vericiguat

Products Affected

- VERQUVO ORAL TABLET 10 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vimseltinib - Oral Oncology

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vismodegib - Oral Oncology

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Voclosporin

Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Vorasidenib - Oral Oncology

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Voriconazole - Voriconazole (IV)

Products Affected

- *voriconazole intravenous recon soln*
- *voriconazole-hpbcd*

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling and excluded for any non-FDA approved or non-medically accepted use, including, but not limited to, preparations such as foot baths, nasal rinses, and mouthwashes.
Required Medical Information	Diagnosis, culture results showing presence of susceptible fungal elements.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	Must be prescribed by an infectious disease specialist or other prescriber specializing in the organ system affected by fungal infection.
Coverage Duration	Initial - 3 mos. Recert: 3 mos if specialist attestation of need for prolonged duration of therapy.
Other Criteria	Covered for FDA approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Vorinostat - Oral Oncology

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Zanubrutinib - BTKi

Products Affected

- BRUKINSA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Zidesamtinib - oral oncology

Products Affected

- JIDEYTRO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	As limited by FDA labeling
Required Medical Information	Diagnosis supported by diagnostic tests and/or laboratory results in accordance with NCCN guidelines. Documentation includes both current and prior therapies administered for the specified condition.
Age Restrictions	Patient age must be consistent with the FDA approval for the stated diagnosis.
Prescriber Restrictions	For cancer diagnosis, must be prescribed by an oncologist or hematologist, or urologist in the case of prostate cancer. For non-cancer diagnosis, must be prescribed by an appropriate specialist.
Coverage Duration	One year
Other Criteria	Covered for FDA-approved indications. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. Renewal criteria: documentation that disease progression has not occurred.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Ziftomenib - Oral Oncology

Products Affected

- KOMZIFTI

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

Zongertinib - Oral Oncology

Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
Exclusion Criteria	PENDING CMS REVIEW
Required Medical Information	PENDING CMS REVIEW
Age Restrictions	PENDING CMS REVIEW
Prescriber Restrictions	PENDING CMS REVIEW
Coverage Duration	PENDING CMS REVIEW
Other Criteria	PENDING CMS REVIEW
Indications	PENDING CMS REVIEW
Off Label Uses	PENDING CMS REVIEW
Part B Prerequisite	PENDING CMS REVIEW
Prerequisite Therapy Required	PENDING CMS REVIEW

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