ACROMEGALY THERAPY - CDCARE CY26

MEDICATION(S)

SOMAVERT

PENDING CMS APPROVAL

ACTHAR - CDCARE CY26

MEDICATION(S)

ACTHAR, ACTHAR GEL, CORTROPHIN, CORTROPHIN GEL

PENDING CMS APPROVAL

ACTIMMUNE - CDCARE CY26

MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ACTINIC KERATOSIS - CDCARE CY26

MEDICATION(S)

DICLOFENAC SODIUM 3 % GEL

PENDING CMS APPROVAL

ACUTE HAE - CDCARE CY26

MEDICATION(S)
ICATIBANT ACETATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded for the prophylaxis of hereditary angioedema attacks.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ADALIMUMAB - CDCARE CY26

MEDICATION(S)

HADLIMA, HADLIMA PUSHTOUCH, SIMLANDI (1 PEN), SIMLANDI (1 SYRINGE), SIMLANDI (2 PEN), SIMLANDI (2 SYRINGE)

PENDING CMS APPROVAL

ALPHA-1 ANTITRYPSIN THERAPY - CDCARE CY26

MEDICATION(S)
PROLASTIN-C

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis, pertinent lab/diagnostic test results (such as AAT serum levels, genotype testing, and pulmonary function testing, or other tests performed to confirm the diagnosis, and documentation of previous therapies

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a pulmonologist

COVERAGE DURATION
One year, only as weekly infusions.

OTHER CRITERIA
Coverage will not be provided for alpha antitrypsin deficits other than the ones defined here: patients with alpha 1 antitrypsin (AAT) levels below 11 micromol/L (80mg/dL or approximately 57mg/dL by nephelometry) who are PiZZ, PiSZ, PiZ(null), Pi(null)(null), Pi(malton,malton), Pi(Siiyama,Siiyama) or have dysfunctional AAT protein (such as PiF or Pi Pittsburg genotypes) AND have evidence of emphysema as FEV1 less than 80% of predicted value. Patients must also demonstrate 1 or more of the following: signs of significant lung disease such as chronic productive cough or unusual frequency of lower respiratory infection, airflow obstruction, accelerated decline of FEV1 or chest radiograph or CT scan evidence of emphysema, especially in the absence of a recognized risk factor (smoking, occupational dust exposure, etc.). In addition, patients with emphysema due to AAT deficiency must be

maintained on regimens similar to those patients with emphysema not associated with AAT deficiency, including: maximally tolerated doses of beta-adrenergic bronchodilators, anticholinergics and antibiotics, when appropriate and no contraindications exist. Request will also 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.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

AMPHETAMINE - CDCARE CY26

MEDICATION(S)
AMPHETAMINE SULFATE, METHAMPHETAMINE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded when used for weight loss, even if non-cosmetic (such as morbid obesity).

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

APOMORPHINE - CDCARE CY26

MEDICATION(S)

APOMORPHINE HCL 30 MG/3ML SOLN CART

PENDING CMS APPROVAL

ARCALYST - CDCARE CY26

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ARIKAYCE - CDCARE CY26

MEDICATION(S)
ARIKAYCE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded when used for the treatment of patients with non-refractory mycobacterium avium complex (MAC) disease or when being used as a single agent.

REQUIRED MEDICAL INFORMATION
Diagnosis, submission of positive sputum culture result obtained after a minimum 6-month treatment with a multi-drug regimen (such as clarithromycin/azithromycin, rifampin, and ethambutol), attestation patient will be using Arikayce in combination with other medications as part of a multi-drug regimen.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an infectious disease specialist or pulmonologist.

COVERAGE DURATION
Initial approval - 6 months. Recertifications - 1 year.

OTHER CRITERIA
Recertification will require documentation of a negative sputum culture while using Arikayce taken within 30 days prior to the recertification request. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

ATTRUBY - CDCARE CY26

MEDICATION(S)
ATTRUBY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic tests, including tests confirming presence of TTR amyloid in cardiac tissue such as 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a specialist experienced in the diagnosis of Transthyretin-mediated Amyloidosis (ATTR-CM), such as a cardiologist.

COVERAGE DURATION
One year.

OTHER CRITERIA
Covered for patients with a diagnosis of cardiomyopathy of wild-type (wtATTR-CM) or Hereditary Transthyretin-mediated Amyloidosis (hATTR-CM). Patient must have a medical history of NYHA class I-III heart failure with at least one prior hospitalization for heart failure or clinical evidence of heart failure requiring treatment with a diuretic for improvement. Evidence of cardiac involvement seen on echocardiography and/or cardiac magnetic imaging, such as thickened left ventricle wall or septum, must be provided. Presence of TTR amyloid in cardiac tissue must be confirmed via 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or

via genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein correlated with amyloid deposits identified on cardiac biopsy. Upon recertification, there must be documentation that the patient continues to obtain clinical benefit from the therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

AUSTEDO - CDCARE CY26

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION 12 & 18 & 24 & 30 MG TBER THPK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Will not be covered in combination with tetrabenazine (Xenazine).

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

MEDICATION(S)

ASENAPINE MALEATE, AUVELITY, CAPLYTA, COBENFY, COBENFY STARTER PACK, FANAPT, FANAPT TITRATION PACK A, FANAPT TITRATION PACK B, FANAPT TITRATION PACK C, OPIPZA, REXULTI, SECUADO, VRAYLAR 1.5 MG CAP, VRAYLAR 3 MG CAP, VRAYLAR 4.5 MG CAP, VRAYLAR 6 MG CAP

PENDING CMS APPROVAL

BENLYSTA - CDCARE CY26

MEDICATION(S)

BENLYSTA 200 MG/ML SOLN A-INJ, BENLYSTA 200 MG/ML SOLN PRSYR

PENDING CMS APPROVAL

BESREMI - CDCARE CY26

MEDICATION(S)

BESREMI

PENDING CMS APPROVAL

BEXAROTENE GEL - CDCARE CY26

MEDICATION(S)

BEXAROTENE 1 % GEL

PENDING CMS APPROVAL

BOTOX - CDCARE CY26

MEDICATION(S)
BOTOX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

BRAF/MEK - CDCARE CY26

MEDICATION(S)

BRAFTOVI, COTELLIC, MEKINIST, MEKTOVI, TAFINLAR, ZELBORAF

PENDING CMS APPROVAL

BRINSUPRI - CDCARE CY26

MEDICATION(S)

BRINSUPRI

PENDING CMS APPROVAL

BTKI - CDCARE CY26

MEDICATION(S)

BRUKINSA, CALQUENCE, IMBRUVICA, JAYPIRCA

PENDING CMS APPROVAL

BUDESONIDE FOAM - CDCARE CY26

MEDICATION(S)

BUDESONIDE 2 MG FOAM, BUDESONIDE 2 MG/ACT FOAM

PENDING CMS APPROVAL

BYLVAY - CDCARE CY26

MEDICATION(S)

BYLVAY, BYLVAY (PELLETS)

PENDING CMS APPROVAL

CABLIVI - CDCARE CY26

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

CARBAGLU - CDCARE CY26

MEDICATION(S)
CARGLUMIC ACID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

CDK 4/6 - CDCARE CY26

MEDICATION(S)

IBRANCE, KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (200 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), VERZENIO

PENDING CMS APPROVAL

CERDELGA - CDCARE CY26

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination therapy with Cerdelga and enzyme replacement therapy (such as Eleyso, Cerezyme) is excluded. Concomitant use of a moderate or strong CYP2D6 inhibitor with a moderate or strong CYP3a inhibitor in extensive metabolizers or intermediate metabolizers is excluded. Concomitant use of a strong CYP3a inhibitor in poor metabolizers or intermediate metabolizers is excluded. Cerdelga is excluded in patients with pre-existing cardiac disease, long Q-T syndrome, and for those who take class 1a or class III antiarrhythmic.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results (such as enzyme analysis, mutation analysis, or bone marrow studies, or other tests performed to confirm the diagnosis). Current drug profile to avoid labeled exclusions for use with enzyme replacement therapy, strong CYP3a inhibitors, and certain antiarrhythmics.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year.

OTHER CRITERIA
Cerdelga is covered for Type 1 Gaucher disease in patients who are CYP2D6 extensive metabolizers, intermediate metabolizers or poor metabolizers.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

CGRP ANTAGONISTS - CDCARE CY26

MEDICATION(S)

AIMOVIG

PENDING CMS APPROVAL

CHOLBAM - CDCARE CY26

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis and pertinent lab/diagnostic test results (such as gas chromatography-mass spectrometry urine analysis, liver function tests and other tests performed to confirm the diagnosis).

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an endocrinologist, gastroenterologist, geneticist, hepatologist, or metabolic specialist.

COVERAGE DURATION
Initial approval - 3 months. Recertifications - 1 year.

OTHER CRITERIA
For its FDA approved indications, there must be a diagnosis made by gas chromatography-mass spectrometry analysis of the urine with a positive identification of elevated bile acids. In addition, liver function tests must identify elevated serum aminotransferases with normal serum gamma glutamyltransferase. The initial approval will be for three months. After the initial three-month authorization, approval will be granted in one-year increments with documentation of improved liver function via aminotransferase lowering. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

CHORIONIC GONADOTROPIN - CDCARE CY26

MEDICATION(S)
NOVAREL 10000 UNIT RECON SOLN, PREGNYL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

CLOMIPHENE - CDCARE CY26

MEDICATION(S)
CLOMIPHENE CITRATE 50 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded when used to promote fertility.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

COSENTYX - CDCARE CY26

MEDICATION(S)

COSENTYX 150 MG/ML SOLN PRSYR, COSENTYX 75 MG/0.5ML SOLN PRSYR, COSENTYX (300 MG DOSE), COSENTYX SENSOREADY (300 MG), COSENTYX SENSOREADY PEN, COSENTYX UNOREADY

PENDING CMS APPROVAL

CUVRIOR - CDCARE CY26

MEDICATION(S)

CUVRIOR

PENDING CMS APPROVAL

DAYBUE - CDCARE CY26

MEDICATION(S)
DAYBUE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by genetic testing showing disease-causing mutation in MECP2.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist or provider who specializes in the treatment of Rett Syndrome (RTT)

COVERAGE DURATION
6 months

OTHER CRITERIA
Covered for patients with a diagnosis of classic or typical Rett Syndrome (RTT) and have a confirmed mutation of the MECP2 gene. Recertification will require subjective or objective evidence from provider that the patient is tolerating therapy and the drug is providing ongoing benefit in terms of disease improvement or stability (i.e., symptoms, quality of life measures, and/or functional measures). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

DEFLAZACORT - CDCARE CY26

MEDICATION(S)
DEFLAZACORT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, current and previous therapies for stated diagnosis, results of Duchenne Muscular Dystrophy (DMD) gene mutation study

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist.

COVERAGE DURATION
One year.

OTHER CRITERIA
Covered for all FDA approved indications with required documentation of significant side effects resulting from a minimum 3-month trial of oral prednisone. Examples of significant prednisone side effects include cushingoid appearance, central (truncal) obesity, undesirable weight gain, inability to manage diabetes or hypertension, steroid-induced mania, or sepsis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

DICHLORPHENAMIDE - CDCARE CY26

MEDICATION(S)
DICHLORPHENAMIDE, ORMALVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

DIHYDROERGOTAMINE - CDCARE CY26

MEDICATION(S)

DIHYDROERGOTAMINE MESYLATE 4 MG/ML SOLUTION

PENDING CMS APPROVAL

DOJOLVI - CDCARE CY26

MEDICATION(S)

DOJOLVI

PENDING CMS APPROVAL

DOPTELET - CDCARE CY26

MEDICATION(S)
DOPTELET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a hematologist, gastroenterologist, hepatologist, or surgeon.

COVERAGE DURATION
One month for chronic liver disease-associated thrombocytopenia. Two years for chronic ITP.

OTHER CRITERIA
Covered for a diagnosis of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure. For this diagnosis, platelet count must be less than 50,000 platelets per microliter. Covered for a diagnosis of chronic immune thrombocytopenia purpura (ITP) in patients who have experienced an insufficient response to previous treatment with either a corticosteroid or immunoglobulin therapy (IVIG). Insufficient response is defined as a platelet count of less than 30,000/microliter or greater than 30,000/microliter but with bleeding symptoms. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

DOXEPIN TOPICAL CREAM - CDCARE CY26

MEDICATION(S)
DOXEPIN HCL 5 % CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

DRONABINOL - CDCARE CY26

MEDICATION(S)

DRONABINOL

PENDING CMS APPROVAL

DROXIDOPA - CDCARE CY26

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

DUPIXENT - CDCARE CY26

MEDICATION(S)

DUPIXENT

PENDING CMS APPROVAL

ENBREL - CDCARE CY26

MEDICATION(S)

ENBREL, ENBREL MINI, ENBREL SURECLICK

PENDING CMS APPROVAL

ENDARI - CDCARE CY26

MEDICATION(S)

L-GLUTAMINE 5 GM PACKET

PENDING CMS APPROVAL

ENSPRYNG - CDCARE CY26

MEDICATION(S)

ENSPRYNG

PENDING CMS APPROVAL

EPIDIOLEX - CDCARE CY26

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ERLEADA - CDCARE CY26

MEDICATION(S)

ERLEADA

PENDING CMS APPROVAL

ESRD - CDCARE CY26

MEDICATION(S)
PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, dialysis status (only if diagnosis of end-stage renal disease)

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

EVENITY - CDCARE CY26

MEDICATION(S)
EVENITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, DEXA scan report(s), previous therapies

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year (refer to other criteria section).

OTHER CRITERIA
Covered for post-menopausal women at high risk for fracture. The patient must be considered high risk for fracture, which is defined as 1) history of previous osteoporosis-related fracture, 2) T- score of -2.5 SD or less, 3) T-score between -1.0 and -2.5 SD below normal and a FRAX score for hip fracture of 3% or greater or the risk for other bone fracture is 20% or greater. Patient must also have experienced therapeutic failure, severe intolerance or a contraindication to an oral bisphosphonate or be an inappropriate candidate for oral bisphosphonate therapy based on clinical presentation. Therapeutic failure is defined as a decrease in bone mineral density or a fracture while on bisphosphonate therapy. Severe intolerance defined as chest pain, difficulty swallowing, intense abdominal pain or chronic dyspepsia when oral bisphosphonate therapy was taken according to manufacturer recommendations. Oral bisphosphonates may be clinically inappropriate for a patient that is bedridden/unable to sit upright for 30 minutes unsupervised or has esophageal ulcerations, esophageal stricture, Barrett's

Esophagitis, or active ulcers. Additionally, patient must have documented severe intolerance or contraindication to generic teriparatide. The FDA approved labeling does not recommend duration to exceed more than 12 monthly doses. Request will also be evaluated for part b versus part d coverage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

EVRYSDI - CDCARE CY26

MEDICATION(S)

EVRYSDI

PENDING CMS APPROVAL

FILSPARI - CDCARE CY26

MEDICATION(S)

FILSPARI

PENDING CMS APPROVAL

FINTEPLA - CDCARE CY26

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

FIRDAPSE - CDCARE CY26

MEDICATION(S)
FIRDAPSE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic test results

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist or neuromuscular specialist

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for patients with a diagnosis of Lambert-Eaton Myasthenic Syndrome that has been confirmed by electromyography or calcium channel antibody testing. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

GABAPENTIN ER - CDCARE CY26

MEDICATION(S)

GABAPENTIN (ONCE-DAILY)

PENDING CMS APPROVAL

GATTEX - CDCARE CY26

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis and evidence of dependency on parenteral nutrition support.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

GLP-1 AGONISTS - CDCARE CY26

MEDICATION(S)
OZEMPIC (0.25 OR 0.5 MG/DOSE), OZEMPIC (1 MG/DOSE), OZEMPIC (2 MG/DOSE), RYBELSUS, TRULICITY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded for weight management and as limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for the treatment of type 2 diabetes mellitus. Excluded for use in weight management. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

GONADOTROPIN RELEASING HORMONE ANALOGS - CDCARE CY26

MEDICATION(S)
ELIGARD, LEUPROLIDE ACETATE 1 MG/0.2ML KIT, LEUPROLIDE ACETATE (3 MONTH), LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT (4-MONTH), LUPRON DEPOT (6-MONTH), LUPRON DEPOT-PED (1-MONTH), LUPRON DEPOT-PED (3-MONTH), LUPRON DEPOT-PED (6-MONTH), TRELSTAR MIXJECT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
6 months for endometriosis. One year for all other diagnoses.

OTHER CRITERIA
Lupron/leuprolide is covered for management of endometriosis, including pain relief and reduction of endometriotic lesions. Authorization will be for up to 6 months, because of a lack of safety data with long term use and concerns regarding effects on bone density. Lupron/leuprolide is covered for treatment of advanced prostate cancer, defined as stage III or stage IV. Lupron/leuprolide is covered for treatment of precocious puberty. Lupron/leuprolide is covered as adjunct therapy for preoperative hematologic improvements of patients with anemia (hematocrit less than or equal to 30% and or hemoglobin less than or equal to 10.2 g/dL) caused by uterine leiomyomata. Eligard and Trelstar are covered for treatment of advanced prostate cancer. Requests will also be evaluated for off-label use.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

GROWTH HORMONE - CDCARE CY26

MEDICATION(S)
OMNITROPE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
When used to increase height, growth hormone therapy will not be covered in pediatric patients with closed epiphyses.

REQUIRED MEDICAL INFORMATION
General-growth charts, height/weight, height velocity. Somatotropin deficiency in children requires documentation of diminished growth hormone response (max peak less than 10ng/mL) to 2 or more different provocation tests (such as levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon) or documentation of low IGF-1 or IGFBP3 for age, sex, and pubertal status in children age 6 or greater in the absence of chronic disease along with a height velocity less than 25th percentile in the 6-12 months prior to growth hormone therapy. In addition to one of the above findings there must also be documentation of two of the following: 1) growth velocity less than 7cm/yr before age three 2) bone age at least 2 SD below normal for chronological age 3) a known risk factor for growth hormone deficiency (such as congenital hypopituitarism, panhypopituitarism, or prior brain radiation). Somatotropin deficiency in adults requires documentation of negative response to provocative test with max peak of 5ng/mL along with documentation of clinical symptoms such as increased weight and body fat mass, decreased lean body mass, decreased exercise tolerance, decreased muscle mass and strength, reduced cardiac performance, reduced bone density, poor sleep, impaired sense of well-being or lack of motivation. Alternatively, will accept insulin tolerance test with max peak less than 5ng/mL (unless contraindicated in which case will accept IV arginine in combination with GH-releasing hormone with max peak less than 10ng/mL.) If there is documentation of deficiency of 3 or more pituitary hormones, ITT or arginine tests are not required. Recertification- in children requires the following every 12 months: current growth velocity, growth charts (height and weight), current bone age, puberty status, and radiographic testing to determine if epiphyses are closed at age 14 in girls and age 16 in boys.

AGE RESTRICTION

Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION

Must be prescribed by an endocrinologist, pediatric endocrinologist, nephrologist, infectious disease specialist, or gastroenterologist.

COVERAGE DURATION

One year

OTHER CRITERIA

Children-covered for treatment of short stature in Turner Syndrome. Covered for children with height less than 3rd percentile for chronological age with renal insufficiency defined as serum creatinine greater than 3.0 mg/dL or creatinine clearance of 5-75 mL/min per 1.73m3 before renal transplant. Covered for Prader-Willi syndrome with short stature or growth failure. Covered for children with intrauterine growth failure or small for gestational age who do not catch up by 2 years of age. Covered for Noonan Syndrome with short stature (when height is at least 2 SD below normal. Covered for children with SHOX deficiency demonstrated by chromosome analysis and whose epiphyses are not closed. Adults and children- growth hormone therapy is covered for a diagnosis of somatotropin deficiency (see required medical info). Covered for AIDS wasting or cachexia or children with HIV associated failure to thrive defined as a greater than 10% of baseline weight loss or weight less than 90% of ideal body weight and either chronic diarrhea or chronic weakness not otherwise explained. Covered for patients with short bowel syndrome who are experiencing malabsorption, malnutrition, weight loss or dehydration despite specialized nutritional support.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

HYFTOR - CDCARE CY26

MEDICATION(S)
HYFTOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a dermatologist, neurologist, or geneticist.

COVERAGE DURATION
Initial 3 months. Recertifications 6 months.

OTHER CRITERIA
Covered for treatment of facial angiofibroma associated with tuberous sclerosis. Patient must have three or more angiofibroma papules at baseline (each at least 2 mm in diameter and with redness) on the face. Initial recertification requires provider documentation of objective and/or subjective evidence of reduced angiofibroma size and/or redness resulting from use of Hyftor. Subsequent recertifications require providers objective and/or subjective evidence that use of Hyftor has provided patient with continued stability or further improvement from status noted at initial recertification. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

IMPAVIDO - CDCARE CY26

MEDICATION(S)
IMPAVIDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy or as limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic test results

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by or recommended by an infectious disease specialist

COVERAGE DURATION
28 days.

OTHER CRITERIA
Covered for the treatment of visceral (caused by Leishmania donovani), cutaneous (caused by L. braziliensis, L. guyanensis, and L. panamensis), and mucosal leishmaniasis (caused by L. braziliensis) in patients weighing at least 30 kg. Efficacy of Impavido in the treatment of other Leishmania species has not been evaluated and therefore not covered. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INCRELEX - CDCARE CY26

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Increlex will not be covered for growth promotion in patients with closed epiphyses or as a substitute for growth hormone replacement therapy. IV administration will not be covered.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results (such as IGF-1 levels and GH levels).

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an endocrinologist, pediatric endocrinologist, or nephrologist.

COVERAGE DURATION
One year

OTHER CRITERIA
Increlex will be covered in patients with severe primary IGF-1 deficiency defined as height SD score less than -3.0, basal IGF-1 SD score less than -3.0, and normal or elevated GH. They will also be covered in patients with growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH. Normal dose is 40-120mcg/kg sq twice daily given 20 minutes before or after a meal or snack to avoid hypoglycemia. Doses greater than 120mcg/kg will not be covered.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

INGREZZA - CDCARE CY26

MEDICATION(S)
INGREZZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INJECTABLE ONCOLOGY - CDCARE CY26

MEDICATION(S)
ELREXFIO, PHESGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ISTURISA - CDCARE CY26

MEDICATION(S)

ISTURISA

PENDING CMS APPROVAL

IVIG - CDCARE CY26

MEDICATION(S)
GAMMAGARD, GAMMAKED, GAMUNEX-C, OCTAGAM 1 GM/20ML SOLUTION, OCTAGAM 10 GM/100ML SOLUTION, OCTAGAM 10 GM/200ML SOLUTION, OCTAGAM 2 GM/20ML SOLUTION, OCTAGAM 2.5 GM/50ML SOLUTION, OCTAGAM 20 GM/200ML SOLUTION, OCTAGAM 30 GM/300ML SOLUTION, OCTAGAM 5 GM/100ML SOLUTION, PRIVIGEN 10 GM/100ML SOLUTION, PRIVIGEN 20 GM/200ML SOLUTION, PRIVIGEN 40 GM/400ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

JOENJA - CDCARE CY26

MEDICATION(S)

JOENJA

PENDING CMS APPROVAL

JOURNAVX - CDCARE CY26

MEDICATION(S)
JOURNAVX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

JUXTAPID - CDCARE CY26

MEDICATION(S)

JUXTAPID

PENDING CMS APPROVAL

KALYDECO - CDCARE CY26

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Coverage will be excluded in patients with cystic fibrosis who are homozygous for the F508 del mutation in the CFTR gene.

REQUIRED MEDICAL INFORMATION
Diagnosis, lab/diagnostic results to include testing for CFTR gene mutation that is responsive to ivacaftor

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

KERENDIA - CDCARE CY26

MEDICATION(S)

KERENDIA

PENDING CMS APPROVAL

KEVZARA - CDCARE CY26

MEDICATION(S)

KEVZARA

PENDING CMS APPROVAL

KINERET - CDCARE CY26

MEDICATION(S)
KINERET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an appropriate specialist to treat the stated diagnosis.

COVERAGE DURATION
One year.

OTHER CRITERIA
Covered for the treatment of moderate to severe RHEUMATOID ARTHRITIS for patients with documented failure to TWO of the following alternatives: Hadlima, Orencia, Rinvoq, Simlandi, Xeljanz/XR. Covered for the diagnosis of neonatal-onset multisystem inflammatory disease (NOMID). Covered for a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) in patients who have a confirmed mutation in the IL1RN gene. Recertification will require provider attestation that the patient has maintained a response to treatment. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

LIDOCAINE PATCH - CDCARE CY26

MEDICATION(S)
LIDOCAINE 5 % PATCH, TRIDACAINE III

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

LIVMARLI - CDCARE CY26

MEDICATION(S)
LIVMARLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Genetic testing confirming Alagille Syndrome (ALGS) or progressive familial intrahepatic cholestasis (PFIC) is required. Note: per FDA-approved prescribing information, Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein. Therefore, Livmarli will not be approved for this subgroup of patients. Evidence of cholestasis (ONE of the following) must be provided: 1) total serum bile acid greater than the ULN for age, or 2) increased conjugated bilirubin levels or 3) otherwise unexplainable fat-soluble vitamin deficiency, or 4) gamma glutamyl transferase (GGT) greater than the ULN for age or 5) intractable pruritus explainable only by liver disease.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by provider experienced with the management of ALGS or PFIC.

COVERAGE DURATION
Initial approval - 6 months. Recertifications - 1 year.

OTHER CRITERIA
Covered for treatment of cholestatic pruritus in patients with genetic testing confirmed ALGS. Covered for treatment of cholestatic pruritus with PFIC. For either indication, objective and/or subjective evidence of significant pruritus must be submitted by provider. Evidence of cholestasis must be provided (as described in required medical information). Recertification requires documentation of a

decrease in pruritus from baseline and/or decrease in serum bile acid concentration from baseline. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

LUPKYNIS - CDCARE CY26

MEDICATION(S)
LUPKYNIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, kidney biopsy results, baseline urine protein/creatinine ratio (UPCR) at time of request, baseline eGFR at time of request, current and previous therapies used for the treatment of the stated diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a rheumatologist or nephrologist

COVERAGE DURATION
Initial approval - 6 months. Recertifications - 1 year.

OTHER CRITERIA
Covered for patients with a diagnosis of class III, IV, or V lupus nephritis (LN) confirmed by kidney biopsy. Patient must be established and continue on standard therapy with mycophenolate/MMF and corticosteroids. Lupkynis is not approved for use as monotherapy or with cyclophosphamide-based immunosuppressive therapy. Also, patient must have had previous trial and failure or severe intolerance with Benlysta/belimumab, used either for systemic lupus erythematosus (SLE) or LN. Recertification after initial 6-month approval requires reduction in UPCR from baseline and increase in eGFR from baseline. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

LYBALVI - CDCARE CY26

MEDICATION(S)

LYBALVI

PENDING CMS APPROVAL

MAVYRET - CDCARE CY26

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Mavyret will not be covered in patients with moderate or severe hepatic impairment (Child-Pugh B or C). Mavyret will not be covered for genotypes that are not supported by its FDA approved indication, compendia, or AASLD guidelines.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic test results including baseline HCV RNA results and HCV genotype, and documentation of current and previous therapies (if applicable).

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or HCV/HIV specialist

COVERAGE DURATION
8 to 16 weeks (depending on diagnosis, FDA approved labeling, and AASLD/IDSA guidance)

OTHER CRITERIA
For off-label Mavyret reviews, criteria will be applied consistent with compendia and current AASLD/IDSA guidance.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

MEMANTINE-DONEPEZIL - CDCARE CY26

MEDICATION(S)

MEMANTINE HCL-DONEPEZIL HCL

PENDING CMS APPROVAL

MIFEPRISTONE - CDCARE CY26

MEDICATION(S)
MIFEPRISTONE 300 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded in patients who are pregnant, who have a history of unexplained vaginal bleeding/endometrial changes, who are currently receiving long-term corticosteroids, or who are currently on simvastatin, lovastatin or a medication that is a CYP3a substrate and has a narrow therapeutic range.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis, pertinent lab/diagnostic test results (such as HbA1c levels and negative pregnancy test in women of childbearing age), and documentation of previous therapies (failure of surgery or not a candidate for surgery).

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an endocrinologist.

COVERAGE DURATION
One year

OTHER CRITERIA
Covered in patients with a diagnosis of endogenous Cushing's syndrome and Type 2 diabetes or glucose intolerance. Patients must have failed surgery or not be a candidate for surgery. Women of childbearing age must have a negative pregnancy test prior to starting therapy and must not be nursing. Non-hormonal contraception must be used while on therapy, unless the patient has had a surgical sterilization, in which case, no additional contraception is needed. Hypokalemia should be corrected prior to treatment and monitored for during treatment. Patients should also be closely

monitored for signs and symptoms of adrenal insufficiency. Recertification after one year will require the submission of patient progress notes and lab work that demonstrates clinical response or stabilization of disease. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

MIGLUSTAT - CDCARE CY26

MEDICATION(S)

MIGLUSTAT

PENDING CMS APPROVAL

MIGRAINE OTHER - CDCARE CY26

MEDICATION(S)

NURTEC

PENDING CMS APPROVAL

MOTPOLY XR - CDCARE CY26

MEDICATION(S)

MOTPOLY XR

PENDING CMS APPROVAL

MYALEPT - CDCARE CY26

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

MYTESI - CDCARE CY26

MEDICATION(S)

MYTESI

PENDING CMS APPROVAL

NITISINONE - CDCARE CY26

MEDICATION(S)

NITISINONE, NITYR

PENDING CMS APPROVAL

NUEDEXTA - CDCARE CY26

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year

OTHER CRITERIA
Requests will also be evaluated for off-label use.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

NUPLAZID - CDCARE CY26

MEDICATION(S)

NUPLAZID

PENDING CMS APPROVAL

OFEV - CDCARE CY26

MEDICATION(S)

OFEV

PENDING CMS APPROVAL

ONYCHOMYCOSIS - CDCARE CY26

MEDICATION(S)
TAVABOROLE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis, KOH stain or culture results showing presence of trichophyton rubrum or trichophyton mentagrophytes, and documentation of previous therapies

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year.

OTHER CRITERIA
Covered for the treatment of onychomycosis of the toenails in patients with documented culture or KOH stain positive for Trichophyton rubrum or Trichophyton mentagrophytes. Additionally, unless contraindicated, documentation of failure or severe intolerance to a course of oral terbinafine must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

OPIOID-INDUCED CONSTIPATION - CDCARE CY26

MEDICATION(S)

RELISTOR, SYMPROIC

PENDING CMS APPROVAL

OPZELURA - CDCARE CY26

MEDICATION(S)

OPZELURA

PENDING CMS APPROVAL

MEDICATION(S)

ABIRATERONE ACETATE 250 MG TAB, AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AVMAPKI FAKZYNJA CO-PACK, AYVAKIT, BALVERSA, BOSULIF, CABOMETYX, CAPRELSA, COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE), COPIKTRA, DASATINIB, DAURISMO, ERIVEDGE, EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GOMEKLI, HERNEXEOS, IBTROZI, ICLUSIG, IDHIFA, IMATINIB MESYLATE 100 MG TAB, IMATINIB MESYLATE 400 MG TAB, IMKELDI, INLYTA, INQOVI, INREBIC, ITOVEBI, IWILFIN, JAKAFI, KOSELUGO, KRAZATI, LAPATINIB DITOSYLATE, LAZCLUZE, LENALIDOMIDE, LENVIMA (10 MG DAILY DOSE), LENVIMA (12 MG DAILY DOSE), LENVIMA (14 MG DAILY DOSE), LENVIMA (18 MG DAILY DOSE), LENVIMA (20 MG DAILY DOSE), LENVIMA (24 MG DAILY DOSE), LENVIMA (4 MG DAILY DOSE), LENVIMA (8 MG DAILY DOSE), LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE), MODEYSO, NERLYNX, NILOTINIB HCL, NINLARO, NUBEQA, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE), POMALYST, QINLOCK, RETEVMO, REVUFORJ, REZLIDHIA, ROMVIMZA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB TOSYLATE, STIVARGA, SUNITINIB MALATE, TABRECTA, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, TIBSOVO, TRUQAP, TUKYSA, TURALIO, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, XALKORI, XOSPATA, XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY), XPOVIO (80 MG TWICE WEEKLY), XTANDI, ZEJULA, ZOLINZA, ZYDELIG, ZYKADIA

PENDING CMS APPROVAL

ORENCIA - CDCARE CY26

MEDICATION(S)

ORENCIA, ORENCIA CLICKJECT

PENDING CMS APPROVAL

ORGOVYX - CDCARE CY26

MEDICATION(S)

ORGOVYX

PENDING CMS APPROVAL

ORIAHNN - CDCARE CY26

MEDICATION(S)
ORIAHNN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, uterine fibroids must be documented by pelvic ultrasound

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a gynecologist

COVERAGE DURATION
Initial approval - 1 year. Recertification - 1 year.

OTHER CRITERIA
Covered for premenopausal female patients with a diagnosis of heavy menstrual bleeding associated with uterine fibroids. Pelvic ultrasound must be provided to confirm diagnosis. Patient must have had serious side effects or drug failure with a contraceptive (such as estrogen-progesterone, progesterone, or hormone-based intrauterine device) and tranexamic acid. Recertification will require objective and/or subjective evidence from provider of improved symptoms. Treatment beyond 24 months (two 12-month courses) will not be approved. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

ORILISSA - CDCARE CY26

MEDICATION(S)

ORILISSA

PENDING CMS APPROVAL

ORKAMBI - CDCARE CY26

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

OTEZLA - CDCARE CY26

MEDICATION(S)

OTEZLA

PENDING CMS APPROVAL

PARKINSONS - CDCARE CY26

MEDICATION(S)

GOCOVRI, INBRIJA, NOURIANZ

PENDING CMS APPROVAL

PART D VS PART B

MEDICATION(S)

ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, AGONEAZE, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, ANZEMET, APREPITANT, ARFORMOTEROL TARTRATE, ASTAGRAF XL, AZATHIOPRINE 100 MG TAB, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE 75 MG TAB, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CALCITONIN (SALMON) 200 UNIT/ACT SOLUTION, CELLCEPT 250 MG CAP, CELLCEPT 500 MG TAB, CINACALCET HCL, CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, ENGERIX-B, ENVARSUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FIASP, FLUOROURACIL 1 GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, GENGRAF 100 MG CAP, GENGRAF 25 MG CAP, GRANISETRON HCL 1 MG TAB, HEPLISAV-B, HUMALOG 100 UNIT/ML SOLUTION, HUMULIN R, HUMULIN R U-500 (CONCENTRATED), IBANDRONATE SODIUM 150 MG TAB, IMOVAX RABIES, INSULIN LISPRO, INTRALIPID, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, KITABIS PAK, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LEVOCARNITINE 330 MG TAB, LEVOCARNITINE (DIETARY) 330 MG TAB, LIDOCAINE-PRILOCAINE, LIVIXIL PAK, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, MYFORTIC, MYHIBBIN, NEORAL 100 MG CAP, NEORAL 25 MG CAP, NOVOLOG, NOVOLOG RELION, OMEGAVEN, ONDANSETRON 4 MG TAB DISP, ONDANSETRON 8 MG TAB DISP, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, PENTAMIDINE ISETHIONATE, PERIKABIVEN, PREHEVBRIO, PREMASOL, PRILOVIX, PRILOVIX LITE, PRILOVIX LITE PLUS, PRILOVIX PLUS, PRILOVIX ULTRALITE, PRILOVIX ULTRALITE PLUS, PROGRAF 0.2 MG PACKET, PROGRAF 0.5 MG CAP, PROGRAF 1 MG CAP, PROGRAF 1 MG PACKET, PROGRAF 5 MG CAP, PROSOL, PULMOZYME, RABAVERT, RAPAMUNE 2 MG TAB, RECOMBIVAX HB, SANDIMMUNE 100 MG CAP,

SANDIMMUNE 25 MG CAP, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SMOFLIPID, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TOBRAMYCIN 300 MG/4ML NEBU SOLN, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TRAVASOL, TRIMETHOBENZAMIDE HCL 300 MG CAP, VARUBI (180 MG DOSE)

DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

PIRFENIDONE - CDCARE CY26

MEDICATION(S)
PIRFENIDONE 267 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis, pertinent lab/diagnostic test results to confirm diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a pulmonologist.

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for a documented diagnosis of idiopathic pulmonary fibrosis.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

PROCYSBI - CDCARE CY26

MEDICATION(S)

PROCYSBI

PENDING CMS APPROVAL

PROMACTA - CDCARE CY26

MEDICATION(S)

ELTROMBOPAG OLAMINE, PROMACTA

PENDING CMS APPROVAL

PROPHYLACTIC HAE - CDCARE CY26

MEDICATION(S)
HAEGARDA, TAKHZYRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded for acute hereditary angioedema attacks.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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. Prophylactic therapy will be covered for individuals whose provider has determined that prophylactic therapy is medically necessary, after consideration of such factors as disease burden, activity of disease, frequency of attacks, patient preference, quality of life, and availability of healthcare resources. Objective and/or subjective documentation of these considerations must be provided. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

PULMONARY HYPERTENSION - CDCARE CY26

MEDICATION(S)

ADEMPAS, AMBRISENTAN, BOSENTAN 125 MG TAB, BOSENTAN 62.5 MG TAB, OPSUMIT, OPSYNVI, ORENITRAM, ORENITRAM MONTH 1, ORENITRAM MONTH 2, ORENITRAM MONTH 3, SILDENAFIL CITRATE 20 MG TAB, TADALAFIL (PAH), UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB, WINREVAIR

PENDING CMS APPROVAL

PYRUKYND - CDCARE CY26

MEDICATION(S)
PYRUKYND, PYRUKYND TAPER PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling. Also, Pyrukynd will not be covered for patients who are homozygous for the c.1436G to A (p.R479H) variant or have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a hematologist, geneticist, or provider who specializes in pyruvate kinase (PK) deficiency

COVERAGE DURATION
6 months

OTHER CRITERIA
Covered for patients with a diagnosis of pyruvate kinase deficiency hemolytic anemia defined as having documented presence of at least 2 mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, one of which is a missense mutation. Baseline hemoglobin must be less than or equal to 10 g/dL OR have had more than 4 red blood cell (RBC) transfusions in the last year. Recert requires ONE of the following: a) improvement in hemoglobin level from baseline OR b) Reduction in the number of RBC transfusions while receiving Pyrukynd OR c) Laboratory evidence demonstrating improvement in markers of hemolysis (i.e., indirect bilirubin, lactate dehydrogenase (LDH), haptoglobin), OR d) other subjective or objective evidence from provider that use of Pyrukynd has

improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

QUININE SULFATE - CDCARE CY26

MEDICATION(S)
QUININE SULFATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded for the treatment of leg cramps.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
6 months

OTHER CRITERIA
Quinine sulfate is covered for the treatment of malaria infections.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

RADICAVA - CDCARE CY26

MEDICATION(S)
RADICAVA ORS, RADICAVA ORS STARTER KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a provider that specializes in Amyotrophic lateral sclerosis (ALS) and/or neuromuscular disorders

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for a diagnosis of Amyotrophic Lateral Sclerosis (ALS) in adult patients. Recertification requires subjective or objective evidence from provider that use of Radicava has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

RECORLEV - CDCARE CY26

MEDICATION(S)

RECORLEV

PENDING CMS APPROVAL

REVCOVI - CDCARE CY26

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

REZDIFFRA - CDCARE CY26

MEDICATION(S)

REZDIFFRA

PENDING CMS APPROVAL

REZUROCK - CDCARE CY26

MEDICATION(S)

REZUROCK

PENDING CMS APPROVAL

RINVOQ - CDCARE CY26

MEDICATION(S)

RINVOQ, RINVOQ LQ

PENDING CMS APPROVAL

SAMSCA - CDCARE CY26

MEDICATION(S)
TOLVAPTAN 30 MG TAB, TOLVAPTAN 15MG (GENERIC SAMSCA)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SAPROPTERIN - CDCARE CY26

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, baseline serum phenylalanine level, current/recent phenylalanine level with each recertification

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

SCIG - CDCARE CY26

MEDICATION(S)
HIZENTRA, HYQVIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SIGNIFOR - CDCARE CY26

MEDICATION(S)

SIGNIFOR

PENDING CMS APPROVAL

SIVEXTRO - CDCARE CY26

MEDICATION(S)
SIVEXTRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis, pertinent lab/diagnostic test results (such as bacterial cultures or antibiotic sensitivity testing), and documentation of previous therapies

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None (see Other Criteria)

COVERAGE DURATION
6 days.

OTHER CRITERIA
Sivextro is covered when prescribed or recommended by an Infectious Disease specialist. When prescribed by any other prescriber, laboratory data including culture site, organism identified and susceptibility must accompany prior-authorization request and documentation must support the trial. In addition, documentation of therapeutic failure of at least one first-line antibacterial agent that is clinically appropriate for the organism identified must be submitted. Approval will be for 6 days of therapy. Requests for non-FDA approved durations of therapy will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

SKYCLARYS - CDCARE CY26

MEDICATION(S)
SKYCLARYS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent diagnostic/genetic test results. Baseline modified Friedreichs Ataxia Rating Scale (mFARS) score must be provided.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist or prescriber knowledgeable in the management of Friedreichs ataxia (FA).

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for patients with a diagnosis of Friedreichs ataxia confirmed by genetic testing. In addition, the patient must exhibit clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling). Recertification requests will require documentation that the patient has had a clinical benefit from therapy (e.g., slowed decline in limb coordination) OR patient has had a reduction in modified Friedreichs Ataxia Rating Scale (mFARS) score of at least 1.5 points from baseline OR provider attestation that the patient continues to benefit from therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

SKYRIZI - CDCARE CY26

MEDICATION(S)

SKYRIZI 150 MG/ML SOLN PRSYR, SKYRIZI 180 MG/1.2ML SOLN CART, SKYRIZI 360 MG/2.4ML SOLN CART, SKYRIZI PEN

PENDING CMS APPROVAL

MEDICATION(S)
ARMODAFINIL, MODAFINIL 100 MG TAB, MODAFINIL 200 MG TAB, SUNOSI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, sleep study results, and documentation of outcome with previous therapies attempted for the stated diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist or sleep specialist for a diagnosis of cataplexy or excessive daytime sleepiness associated with narcolepsy. Must be prescribed by a neurologist, sleep specialist, or pulmonologist for a diagnosis of Excessive Daytime Sleepiness associated with Obstructive Sleep Apnea.

COVERAGE DURATION
One year.

OTHER CRITERIA
Armodafinil and modafinil are covered for a diagnosis of excessive daytime sleepiness associated with narcolepsy, excessive daytime sleepiness associated with obstructive sleep apnea (OSA) and shift-work disorder. Sunosi is covered for a diagnosis of excessive daytime sleepiness associated with narcolepsy for adult patients who have had severe intolerance to or therapeutic failure of both armodafinil and modafinil (armodafinil and modafinil not required in pediatric patients). Sunosi is covered for a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) for patients who have had severe intolerance to or therapeutic failure of both armodafinil and

modafinil. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

SODIUM OXYBATE - CDCARE CY26

MEDICATION(S)

SODIUM OXYBATE

PENDING CMS APPROVAL

SPIRIVA RESPIMAT - CDCARE CY26

MEDICATION(S)

SPIRIVA RESPIMAT

PENDING CMS APPROVAL

SYMDEKO - CDCARE CY26

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

SYNDROS - CDCARE CY26

MEDICATION(S)
SYNDROS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis. For a diagnosis of nausea and vomiting associated with cancer chemotherapy, also list previous therapies.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Anorexia due to AIDS - 1 year. Chemo-induced nausea/vomiting - 6 months.

OTHER CRITERIA
Covered for the treatment of nausea and vomiting associated with cancer chemotherapy with documented lack of response or severe intolerance to one 5HT-3 receptor antagonist. Covered for treatment of anorexia associated with weight loss in patients with AIDS. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

TADALAFIL FOR DAILY USE - CDCARE CY26

MEDICATION(S)

TADALAFIL 2.5 MG TAB, TADALAFIL 5 MG TAB

PENDING CMS APPROVAL

TAFAMIDIS - CDCARE CY26

MEDICATION(S)
VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent lab/diagnostic tests, including tests confirming presence of TTR amyloid in cardiac tissue such as 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a specialist experienced in the diagnosis of Transthyretin-mediated Amyloidosis (ATTR-CM), such as a cardiologist.

COVERAGE DURATION
One year.

OTHER CRITERIA
Covered for patients with a diagnosis of cardiomyopathy of wild-type (wtATTR-CM) or Hereditary Transthyretin-mediated Amyloidosis (hATTR-CM). Patient must have a medical history of NYHA class I-III heart failure with at least one prior hospitalization for heart failure or clinical evidence of heart failure requiring treatment with a diuretic for improvement. Evidence of cardiac involvement seen on echocardiography and/or cardiac magnetic imaging, such as thickened left ventricle wall or septum, must be provided. Presence of TTR amyloid in cardiac tissue must be confirmed via 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or

via genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein correlated with amyloid deposits identified on cardiac biopsy. Upon recertification, there must be documentation that the patient continues to obtain clinical benefit from the therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TARPEYO - CDCARE CY26

MEDICATION(S)

TARPEYO

PENDING CMS APPROVAL

TASIMELTEON - CDCARE CY26

MEDICATION(S)
TASIMELTEON

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting lab/diagnostic test results (such as urinary melatonin and/or cortisol levels or actigraphy over a several week interval). For Smith-Magenis Syndrome (SMS), appropriate genetic testing is also required.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a sleep specialist or neurologist.

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for a diagnosis of non-24-hour sleep-wake disorder for blind individuals who lack light perception. Based on the patient population used in clinical studies evaluating the efficacy of tasimelteon capsules will only be approved in patients with non-24 who are totally blind. Covered for nighttime sleep disturbances in Smith-Magenis syndrome (SMS). For SMS, patients must provide genetic testing confirmation of chromosome 17p11.2 deletion or RAI1 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TAVNEOS - CDCARE CY26

MEDICATION(S)
TAVNEOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, current and previous therapies used for the treatment of the stated diagnosis. Must either have a positive test for antibodies to proteinase 3 (PR3) or myeloperoxidase (MPO) or have histological evidence of GPA or MPA via biopsy.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by a rheumatologist, nephrologist, pulmonologist, or immunologist.

COVERAGE DURATION
Initial approval - 6 months. Recertifications - 1 year.

OTHER CRITERIA
Covered as adjunctive treatment for patients with a diagnosis of active and severe anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]). Tavneos must be used as adjunctive treatment in combination with standard of care therapy (such as cyclophosphamide, azathioprine, mycophenolate mofetil, rituximab, glucocorticoids). Recertification will require documentation of disease remission, defined as the absence of clinical signs or symptoms attributed to GPA or MPA while on Tavneos. Recertification requires that Tavneos continue to be used in combination with standard of care therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TERIPARATIDE - CDCARE CY26

MEDICATION(S)
TERIPARATIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, DEXA scan report(s), previous therapies

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Two years (refer to other criteria section).

OTHER CRITERIA
Patient must fall into one of the following categories: postmenopausal woman, primary or hypogonadal osteoporosis in a male or patient at risk for steroid induced osteoporosis. Patient must also be at high risk for a fracture defined as 1) history of previous osteoporosis-related fracture, 2) T-score of -2.5 SD or less, 3) T-score between -1.0 and -2.5 SD below normal and a FRAX score for hip fracture of 3% or greater or the risk for other bone fracture is 20% or greater. Patient must also have experienced therapeutic failure, severe intolerance or a contraindication to an oral bisphosphonate or be an inappropriate candidate for oral bisphosphonate therapy based on clinical presentation. Therapeutic failure is defined as a decrease in bone mineral density or a fracture while on bisphosphonate therapy. Severe intolerance defined as chest pain, difficulty swallowing, intense abdominal pain, or chronic dyspepsia when oral bisphosphonate therapy was taken according to manufacturer recommendations. Oral bisphosphonates may be clinically inappropriate for a patient that is bed-ridden/unable to sit

upright for 30 minutes unsupervised or has esophageal ulcerations, esophageal stricture, Barrett's esophagitis, or active ulcers. In patients without a trial of or contraindication to oral bisphosphonates, a trial with an injectable bisphosphonate will be accepted in lieu of oral, but is not required. Use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture. Requests for continued therapy beyond 2 years will require provider attestation that the patient has remained at or has returned to having a high risk for fracture. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

THALOMID - CDCARE CY26

MEDICATION(S)
THALOMID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TOCILIZUMAB - CDCARE CY26

MEDICATION(S)

TYENNE 162 MG/0.9ML SOLN A-INJ, TYENNE 162 MG/0.9ML SOLN PRSYR

PENDING CMS APPROVAL

TOLVAPTAN - CDCARE CY26

MEDICATION(S)

TOLVAPTAN, TOLVAPTAN 15MG (GENERIC JYNARQUE)

PENDING CMS APPROVAL

TOPICAL PSORIASIS COMBOS - CDCARE CY26

MEDICATION(S)

CALCIPOTRIENE-BETAMETH DIPROP, DUOBRII, ENSTILAR

PENDING CMS APPROVAL

TOPICAL RETINOIDS - CDCARE CY26

MEDICATION(S)
ADAPALENE 0.1 % CREAM, ADAPALENE 0.3 % GEL, ALTRENO, ARAZLO, FABIOR, TAZAROTENE 0.05 % CREAM, TAZAROTENE 0.05 % GEL, TAZAROTENE 0.1 % CREAM, TAZAROTENE 0.1 % FOAM, TAZAROTENE 0.1 % GEL, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.05 % GEL, TRETINOIN 0.1 % CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded when used for cosmetic purposes.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
One year

OTHER CRITERIA
Adapalene, tazarotene, and tretinoin products will be approved for the diagnosis of acne vulgaris. In addition, tazarotene will be approved for the diagnosis of plaque psoriasis. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

TRIKAFTA - CDCARE CY26

MEDICATION(S)
TRIKAFTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TRIPTODUR - CDCARE CY26

MEDICATION(S)
TRIPTODUR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TYVASO INHALATION - CDCARE CY26

MEDICATION(S)
TYVASO, TYVASO REFILL, TYVASO STARTER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 pro–B-type natriuretic peptide] level.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

URSODIOL - CDCARE CY26

MEDICATION(S)

URSODIOL 200 MG CAP, URSODIOL 400 MG CAP

PENDING CMS APPROVAL

USTEKINUMAB - CDCARE CY26

MEDICATION(S)

SELARSDI 45 MG/0.5ML SOLN PRSYR, SELARSDI 90 MG/ML SOLN PRSYR, STELARA 45 MG/0.5ML SOLN PRSYR, STELARA 45 MG/0.5ML SOLUTION, STELARA 90 MG/ML SOLN PRSYR, USTEKINUMAB 45 MG/0.5ML SOLN PRSYR, USTEKINUMAB 45 MG/0.5ML SOLUTION, USTEKINUMAB 90 MG/ML SOLN PRSYR, YESINTEK 45 MG/0.5ML SOLN PRSYR, YESINTEK 45 MG/0.5ML SOLUTION, YESINTEK 90 MG/ML SOLN PRSYR

PENDING CMS APPROVAL

VALCHLOR - CDCARE CY26

MEDICATION(S)

VALCHLOR

PENDING CMS APPROVAL

VERKAZIA - CDCARE CY26

MEDICATION(S)

VERKAZIA

PENDING CMS APPROVAL

VERQUVO - CDCARE CY26

MEDICATION(S)

VERQUVO

PENDING CMS APPROVAL

VIJOICE - CDCARE CY26

MEDICATION(S)
VIJOICE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an appropriate specialist to treat the stated diagnosis

COVERAGE DURATION
Initial approval - 6 months. Recertifications - 1 year.

OTHER CRITERIA
Covered for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. There must be submitted documentation of a mutation in the PIK3CA gene and the patient must have at least one target lesion identified on imaging at baseline. Recertification will require documentation from provider of objective or subjective evidence that patient has derived clinical benefit from the use of Vijoice. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

VIVJOA - CDCARE CY26

MEDICATION(S)
VIVJOA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling. Vivjoa is contraindicated in those who have the ability to become pregnant, are pregnant, or are lactating.

REQUIRED MEDICAL INFORMATION
Diagnosis, pertinent diagnostic test results, current and previous therapies used for the treatment of the stated diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Limited to one treatment course (14 weeks) per year.

OTHER CRITERIA
Covered for a diagnosis of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential. Females who are not of reproductive potential are defined as persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g. tubal ligation, hysterectomy, salpingo-oophorectomy). The patient must have had 3 or more symptomatic acute episodes of VVC within the past 12 months and must have a KOH stain or other positive diagnostic culture test for this recurrence. In addition, the patient must have experienced an adverse reaction or treatment failure of oral fluconazole at a dosing regimen appropriate for diagnosis of RVVC, unless patient has adverse reaction or contraindication to fluconazole. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use

requirements.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

VORICONAZOLE (IV) - CDCARE CY26

MEDICATION(S)
VORICONAZOLE 200 MG RECON SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

VOWST - CDCARE CY26

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

VYVGART HYTRULO PFS - CDCARE CY26

MEDICATION(S)

VYVGART HYTRULO 1000-10000 MG-UNT/5ML SOLN PRSYR

PENDING CMS APPROVAL

WELIREG - CDCARE CY26

MEDICATION(S)

WELIREG

PENDING CMS APPROVAL

XDEMVY - CDCARE CY26

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Microscopic examination of eyelashes showing Demodex mites.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist.

COVERAGE DURATION
Two months.

OTHER CRITERIA
Must have a diagnosis of Demodex blepharitis confirmed by microscopic examination of the eyelashes to detect Demodex mites. Must have bothersome symptoms of Demodex blepharitis (such as itchy eyelids, excessive eye tearing, light sensitivity, gritty or burning eye sensation). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

XELJANZ - CDCARE CY26

MEDICATION(S)

XELJANZ, XELJANZ XR

PENDING CMS APPROVAL

XENAZINE - CDCARE CY26

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
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.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

XERMELO - CDCARE CY26

MEDICATION(S)

XERMELO

PENDING CMS APPROVAL

XGEVA - CDCARE CY26

MEDICATION(S)

XGEVA

PENDING CMS APPROVAL

XHANCE - CDCARE CY26

MEDICATION(S)

XHANCE

PENDING CMS APPROVAL

XOLAIR - CDCARE CY26

MEDICATION(S)

XOLAIR

PENDING CMS APPROVAL

YONSA - CDCARE CY26

MEDICATION(S)

YONSA

PENDING CMS APPROVAL

ZTALMY - CDCARE CY26

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis, including supporting labs/diagnostic test results.

AGE RESTRICTION
Patient age must be consistent with the FDA approval for the stated diagnosis.

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a neurologist.

COVERAGE DURATION
One year

OTHER CRITERIA
Covered for the treatment of seizures associated with Cyclin-Dependent Kinase-Like 5 (CDKL5) deficiency disorder confirmed by CDKL5 genetic testing in patients 2 years of age and older. Recertification will require either (1) documentation of a sustained reduction in monthly seizure frequency compared to baseline or (2) subjective or objective evidence from provider that use of Ztalmy has improved the patient's condition. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

ZURZUVAE - CDCARE CY26

MEDICATION(S)

ZURZUVAE

PENDING CMS APPROVAL