



Providence

Medicare Advantage Plans

PROVIDENCE MEDICARE ADVANTAGE PLANS

2023 PRIOR AUTHORIZATION CRITERIA FOR PART B DRUGS:

PHIP ALIGN GROUP PLAN + RX (HMO) AND FLEX GROUP PLAN + RX (HMO-POS) PLANS

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For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 or, for TTY users, 711, seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit [ProvidenceHealthAssurance.com/PHIP](https://www.ProvidenceHealthAssurance.com/PHIP).

Medicare Part B Drug Prior Authorization

Our job as your health plan is to make sure that you receive the right care at the right time and at the most affordable price. Providence Medicare Advantage Plans requires you (or your physician) to get approval for certain medical services, including administration of certain medications, before we will agree to cover the drug for you. This is called “prior authorization.” Sometimes the requirement for getting approval in advance helps guide appropriate use of certain drugs including specialty drugs injected or infused by your provider. If you do not get this approval, your drug might not be covered by the plan.

This document contains the Prior Authorization requirements for certain Part B eligible drugs.

For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 (TTY users should call 711), seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit ProvidenceHealthAssurance.com/PHIP.

ACUTE HEREDITARY ANGIOEDEMA THERAPY_ MEDICARE PART B

MEDICATION(S)

BERINERT, KALBITOR, RUCONEST

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), all the following must be met:

a. Diagnosis of Hereditary Angioedema as confirmed by one of the following:

i. For HAE Type I and Type II, documentation of the following (per laboratory standard):

1) Serum C4 level below the lower limit of normal

AND

2) One of the following:

a) C1-Inhibitor (C1-INH) protein level less than 50 percent of the lower limit of normal, or

b) C1-INH protein function less than 50 percent of the lower limit of normal

ii. For HAE with normal C1-INH or HAE Type III:

1) Confirmed Factor 12 (FXII), ANGPT1, PLG, or KNG1 gene mutation, OR

2) Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids

b. For coverage of Berinert®, Kalbitor®, or Ruconest®: Documentation of trial and failure or contraindication to generic icatibant

2. For patients established on the requested therapy (within the previous year):

a. Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE attack episodes.

AGE RESTRICTION

Kalbitor® - 12 years and older

Ruconest® - 13 years and older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an immunologist or an allergist.

COVERAGE DURATION

Initial authorization will be approved for up to six months. Reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

ADAKVEO MEDICARE PART B

MEDICATION(S)

ADAKVEO

COVERED USES

N/A

EXCLUSION CRITERIA

Used in combination with voxelotor (Oxbryta®)

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), all of the following criteria must be met:
 - a. Confirmed medical history or diagnosis of sickle cell disease
 - b. Patient has experienced at least two sickle cell-related pain crises in the prior year
 - c. Documentation that patient meets one of the following:
 - i. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six months
 - ii. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six months
 - iii. Patient has had an intolerance or contraindication to hydroxyurea (For many patients, myelosuppression is dose-dependent and reversible. Intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)
2. For patients established on the requested agent within the previous year: Documentation that the number or severity of sickle cell-related pain crises has decreased from baseline

AGE RESTRICTION

May be approved for patients 16 years of age and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a hematologist or a provider experienced with the treatment of sickle cell disease

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)

ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of:

1. One of the following:

- a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 micromol/L (approximately 50 mg/dL by nephelometry or 80mg/dL by immunodiffusion)
- b. Patient has one of the following high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null)

AND

2. Diagnosis of emphysema with one of the following:

- a. Forced expiratory volume per one second (FEV-1) of 35 to 65% of predicted volume
- b. Rapid lung function decline as evidence by reduction of FEV-1 of 100 mL/year or greater

AND

3. Documentation that the patient has never smoked or has abstained from smoking for at least the previous six months

Reauthorization requires documentation of positive clinical response to therapy (e.g., reduction in exacerbations, reduced progression of emphysema as assessed by computed tomography (CT) densitometry, slowing of FEV-1 decline)

QUANTITY LIMIT:

60 mg/kg infused every seven days, subject to audit.

Note: Dose may be rounded down to the nearest gram (500 mg for Aralast®) within 10% of calculated dose.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

ANTI-AMYLOID MONOCLONAL ANTIBODIES

MEDICATION(S)

ADUHELM, LEQEMBI

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Commercial/Medicaid:

Monoclonal antibodies directed against amyloid is not considered medically necessary and will not be covered due to insufficient evidence of a clinical benefit and safety concerns.

Medicare Part B:

Coverage of the requested drug will be provided in accordance with CMS's National Coverage Analysis: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

N/A

OTHER CRITERIA

N/A

BENLYSTA

MEDICATION(S)

BENLYSTA 120 MG VIAL, BENLYSTA 400 MG VIAL

COVERED USES

N/A

EXCLUSION CRITERIA

Belimumab will not be approved if any of the following are present:

1. Severe active central nervous system lupus
2. Current use of other biologic immunomodulator
3. Documentation of previous use of dialysis in the past 12 months or currently using dialysis
4. Concurrent use of voclosporin (Lupkynis®) or anifrolumab (Saphnelo®)

REQUIRED MEDICAL INFORMATION

For patients initiating therapy for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all the following must be met:

1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist

AND

2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:
 - a. Positive Antinuclear antibody (ANA)
 - b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
 - c. Positive anti-Smith (Anti-Sm)
 - d. Positive anti-Ro/SSA and anti-La/SSB antibodies

AND

3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
 - a. For SLE without Active Lupus Nephritis:
 - i. Oral corticosteroid(s)
 - ii. Azathioprine
 - iii. Methotrexate
 - iv. Mycophenolate mofetil
 - v. Hydroxychloroquine
 - vi. Chloroquine

vii. Cyclophosphamide

b. For SLE with Active Lupus Nephritis:

i. mycophenolate for induction followed by mycophenolate for maintenance, OR

ii. cyclophosphamide for induction followed by azathioprine for maintenance.

4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

For patients established on therapy, the following criteria must be met:

1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events)

2. Patient currently receiving standard therapy for SLE and active lupus nephritis

AGE RESTRICTION

Age five years and older for IV infusion

Age 18 years and older for subcutaneous injection

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a rheumatologist, nephrologist or a provider with experience treating SLE or lupus nephritis

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA

N/A

BOTULINUM TOXIN_ MEDICARE PART B

MEDICATION(S)

BOTOX, BOTOX COSMETIC, DYSPORT, JEUVEAU, MYOBLOC, XEOMIN

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service: Botulinum Toxin

Medicare Guidelines: Local Coverage Determination (LCD) criteria – LCD35172

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

CABENUVA - MEDICARE PART B

MEDICATION(S)

CABENUVA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For new starts:

1. Patient must have a confirmed diagnosis of human immunodeficiency virus type -1 (HIV-1)
2. Patient has been stable and adherent with their current antiviral regimen for a minimum of six (6) months (adherence may be confirmed by pharmacy claims)
3. Patient has a recent viral HIV-1 RNA of less than 50 copies/mL on current oral antiviral regimen
4. Documentation that patient does not have a history of treatment failure

For continuation of therapy:

1. Documentation that patient has been adherent with therapy
2. Documentation that patient has maintained a viral HIV-1 RNA of less than 50 copies/mL

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an infectious disease specialist

COVERAGE DURATION

Initial authorization for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA

N/A

CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE

MEDICATION(S)

DEXCOM G4 RECEIVER, DEXCOM G4 TRANSMITTER, DEXCOM G5 RECEIVER, DEXCOM G5 TRANSMITTER, DEXCOM G5-G4 SENSOR, DEXCOM G6 RECEIVER, DEXCOM G6 SENSOR, DEXCOM G6 TRANSMITTER, DEXCOM RECEIVER, FREESTYLE LIBRE 14 DAY READER, FREESTYLE LIBRE 14 DAY SENSOR, FREESTYLE LIBRE 2 READER, FREESTYLE LIBRE 2 SENSOR

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

I. Continuous glucose monitors may be considered medically necessary and covered for the management of insulin-dependent diabetes when all the following criteria are met:

A. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and

B. The patient is currently using insulin therapy . This may be verified by pharmacy claim(s) for insulin within the previous 120 days.

II. Continuous glucose monitors may be considered medically necessary and covered for patients experiencing post-bariatric hypoglycemia (PBH) when all the following criteria are met:

C. Other causes of hypoglycemia have been ruled out (such as malnutrition, adverse events from medications, dumping syndrome, or insulinoma), and

D. The patient is experiencing severe hypoglycemia episodes or hypoglycemia unawareness

Replacement of Continuous Glucose Monitors

I. Upgrade or replacement of continuous glucose monitor systems may be considered medically necessary and covered when there is documentation that one or more of the device components meet all of the following criteria (A.-C.):

A. Are no longer functional, and

B. Are not under warranty, and

C. Cannot be repaired.

II. Upgrade or replacement of continuous glucose monitor systems is considered not medically necessary and not covered when criterion II above is not met.

Upon approval, concurrent use of test strips will be limited to:

- Dexcom G6/Dexcom G7/Freestyle Libre 2/Libre 3: 50 test strips per 90-day supply

o An additional 50 test strips per 90 days may be approved with documentation that the patient has low blood glucose levels requiring verification at least two times per week (See Diabetic DME policy).

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

CRYSVITA MEDICAL BENEFIT

MEDICATION(S)

CRYSVITA

COVERED USES

N/A

EXCLUSION CRITERIA

Pediatric patients with an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73m² or adult patients with creatinine clearance (CLcr) less than 30 mL/min.

REQUIRED MEDICAL INFORMATION

Initial authorization for new starts all of the following criteria must be met:

1. One of the following diagnoses:
 - a. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following:
 - i. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance
 - ii. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL
 - b. Clinical diagnosis of tumor-induced osteomalacia (TIO) and all of the following:
 - i. Associated with tumors that cannot be identified or curatively resected
 - ii. FGF23 level of at least 100 pg/mL, and
2. Documentation that serum phosphorus level is below the normal range for age, (use laboratory-specific reference ranges if available, otherwise, see appendix for ranges), and
3. One of the following:
 - a. Patient's epiphyseal plate has NOT fused, or
 - b. Patient meets all of the following:
 - i. Patient's epiphyseal plate has fused, and
 - ii. Patient is experiencing clinical signs and symptoms of disease (e.g., limited mobility, musculoskeletal pain, bone fractures), and
4. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced, and
5. Documentation of patient's current weight and that dosing is in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:

1. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
2. Documentation of at least one of the following responses to therapy:

- a. Improvement in skeletal deformities
 - b. Healing of fracture or pseudofractures
 - c. Reduction in number of fractures/pseudofractures
 - d. Increase in growth velocity, and
3. Documentation of patient's current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for hypophosphatemia in tumor induced osteomalacia (TIO) all of the following criteria must be met:

1. Documentation that tumor continues to be unidentifiable or unresectable
2. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
3. Documentation of at least one of the following responses to therapy:
 - a. Improvement in skeletal deformities
 - b. Healing of fracture or pseudofractures
 - c. Reduction in number of fractures/pseudofractures
 - d. Increase in growth velocity, and
4. Documentation of patient's current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders.

COVERAGE DURATION

Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

DURYSTA_MEDICARE PART B

MEDICATION(S)

DURYSTA

COVERED USES

All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

The following criteria must be met:

- 1.The patient is not receiving re-treatment of eye(s) previously treated with bimatoprost intracameral implant (Durysta®)
- 2.Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin

AGE RESTRICTION

Approved for 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by an ophthalmologist

COVERAGE DURATION

Authorization will be approved for 6 months. Approval will be for a one-time use in each treated eye (one implant per treated eye, a total of two implants per patient)

OTHER CRITERIA

N/A

EMPAVELI

MEDICATION(S)

EMPAVELI

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent therapy with another FDA-approved product for PNH, meaning Soliris® or Ultomiris®, unless the member is in a four-week period of cross-titration between Soliris® and Empaveli®

REQUIRED MEDICAL INFORMATION

Paroxysmal Nocturnal Hemoglobinuria (PNH):

1. For initiation of therapy (patients not established on therapy), all the following must be met:
 - a. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycoposphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
 - b. Severe disease as defined by at least one of the following (i or ii):
 - i. Documented history of thrombosis, OR
 - ii. Documentation of at least 10% PNH type III red cells AND at least one of the following:
 1. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
 2. Disabling fatigue
 3. End-organ complications
 4. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
 5. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
2. For patients currently on eculizumab (Soliris®) or ravulizumab (Ultomiris®) switching to pegcetacoplan (Empaveli®) the following must be met:
 - a. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1a above) and severe disease (criteria 1b above). However, this can be based on patient's history prior to starting eculizumab or ravulizumab.
3. For patients already established on the requested therapy, the following must be met for continuation of therapy:
 - a. Documentation of reduced LDH levels, reduced transfusion requirements, increase in hemoglobin levels, or improvement in PNH related symptoms

AGE RESTRICTION

May be approved for patients aged 18 years and older.

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a hematologist/oncologist or nephrologist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

ENJAYMO

MEDICATION(S)

ENJAYMO

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initiation of therapy (new start), all the following must be met:

1. Diagnosis of primary cold agglutinin disease (CAD) by all the following:
 - a. Chronic hemolysis, confirmed by low levels of haptoglobin, and high levels of unconjugated bilirubin and lactate dehydrogenase
 - b. Positive direct antiglobulin (Coombs) test for C3d. (Note: a positive is graded as a 1+, 2+, or 3+)
 - c. Cold agglutinin titer of 1:64 or higher at 4 degrees Celsius
 - d. Presence of one or more symptom associated with CAD such as symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria
2. History of blood transfusion within the previous six months
3. Hemoglobin of 10 g/dL or less
4. Dose and frequency are in accordance with FDA-approved labeling

For patients that are established on therapy, all the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):

1. Diagnosis of cold agglutinin disease
2. Documentation of successful response to therapy defined as an increase in hemoglobin level or reduced transfusion requirements
3. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a hematologist or an oncologist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for a year.

OTHER CRITERIA

N/A

ENZYME REPLACEMENT THERAPY_ MEDICARE PART B

MEDICATION(S)

ALDURAZYME, BRINEURA, CERAZYME, ELAPRASE, ELELYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, VIMIZIM, VPRIV, XENPOZYME

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initiation of therapy (new starts to therapy) all the following criteria must be met:

- 1.Documentation of FDA-labeled indication for the requested product
- 2.Dosing is within FDA-labeled guidelines.
- 3.For avalglucosidase alfa (Nexviazyme®) only: Patients weighing less than 30 kg must have a documented trial, failure, intolerance or contraindication to alglucosidase alfa (Lumizyme®)
- 4.For olipudase alfa (Xenpozyme®) only, the following additional criteria must be met:
 - a.Clinical presentation must be consistent with acid sphingomyelinase deficiency (ASMD) type B OR ASMD type A/B
 - b.Spleen volume of six multiples of normal (MN) or more for adults OR five MN or more for those less than 18 years old
 - c.For adults only, diffusing capacity of the lungs for carbon monoxide (DLco) equal to 70% or less of predicted normal value
 - d.The following are excluded from coverage:
 - i.Use of invasive ventilatory support, or noninvasive ventilatory support while awake for greater than 12 hours a day
 - ii.Acute or rapidly progressive neurological abnormalities and/or genotypes associated with ASMD type A, meaning homozygous for SMPD1 gene mutations R496L, L302P, and fs330 or any combination of these three mutations
- 5.For cerliponase alfa (Brineura®) only, the following additional criteria must be met:
 - a.Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) confirmed by both of the following:
 - i.Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity (in a sample of leukocytes, fibroblasts, dried blood spot or saliva)
 - ii.Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2 gene
 - b.Documentation of symptomatic disease (such as, seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures)
 - c.Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least one

6. For velmanase alfa only, the following additional criteria must be met:

a. Confirmed diagnosis of alpha-mannosidosis as defined by alpha-mannosidase activity less than 10% of normal activity in blood leukocytes

b. Documented baseline serum oligosaccharide level

c. Documented baseline value of either 6-minute walk test, 3-minute stair climb or forced vital capacity.

Note: This may be waived for children under the age of three. Improvement or stabilization is required for reauthorization.

d. Therapy is being used to treat non-central nervous system manifestations of alpha mannosidosis such as skeletal abnormalities, myopathy, motor function disturbances, immune deficiency

e. No prior history of bone marrow transplant

Note: If request is for a non-FDA approved dose, medical rationale must be submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines and exceptions will be considered on a case-by-case basis.

For patients currently established on the requested therapy, all the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).

a. For olipudase alfa (Xenpozyme®) only, documentation of improvement in at least one of the following: spleen volume, liver volume, platelet count, DLco or forced vital capacity (FVC)

b. For cerliponase alfa (Brineura®) only, documentation of both of the following:

i. No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale

ii. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

c. For velmanase alfa (Lamzede®) only, documentation of one of the following:

i. For initial reauthorization: a decrease of serum oligosaccharides of 3 micromoles per liter or at least 30%

ii. For subsequent reauthorizations: stabilization or improvement in either the 6-minute walk test, 3-minute stair climb or forced vital capacity

2. Dosing is within FDA-labeled guidelines

Note: If request is for a non-FDA approved dose, medical rationale must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis.

ii. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

2. Dosing is within FDA-labeled guidelines

Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis.

QUANTITY LIMIT:

Initial dose approval will be based on patient's current weight. Increases in dose will require new authorization with patient's weight and relevant chart notes

AGE RESTRICTION

Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hepatologist, endocrinologist, medical geneticist, cardiologist, pulmonologist, neurologist, or bone and mineral specialist.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

ERYTHROPOIESIS STIMULATING AGENTS (ESAS) _ MEDICARE PART B

MEDICATION(S)

ARANESP, EPOGEN, MIRCERA, PROCRIT, RETACRIT

COVERED USES

N/A

EXCLUSION CRITERIA

- Patients with uncontrolled hypertension
- Anemia in cancer or cancer treatment patients due to folate deficiency (ICD-10: D52.0, D52.1, D52.8, or D52.9), B-12 deficiency (ICD-10: D51.1, D51.2, D51.3, D51.8, D51.9, or D53.1), iron deficiency (ICD-10: D50.0, D50.1, D50.8, and D50.9), hemolysis - (ICD-10: D55.0, D55.1, D58.0, D58.9, D59.0, D59.1, D59.2, D59.4, D59.5, D59.6, D59.8, or D59.9), or active bleeding (ICD-10: D50.0, D62)
- Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (ICD-10: C92.00, C92.01, C92.02, C92.10, C92.11, C92.12, C92.20, C92.21, C92.40, C92.41, C92.42, C92.50, C92.51, C92.52, C92.60, C92.61, C92.62, C92.90, C92.91, C92.A0, C92.A1, C92.A2, C92Z0, C92Z1, or C92Z2), or
- Anemia associated with the treatment of erythroid cancers (ICD-10: C94.00, C94.01, C94.02, C94.20, C94.21, C94.22, C94.30, C94.31, C94.80, C94.81, D45).
- Anemia in cancer or cancer treatment patients due to bone marrow fibrosis
- Anemia of cancer not related to cancer treatment
- Any anemia associated only with radiotherapy
- Prophylactic use to prevent chemotherapy-induced anemia
- Prophylactic use to reduce tumor hypoxia
- Patients with erythropoietin-type resistance due to neutralizing antibodies

REQUIRED MEDICAL INFORMATION

Coverage criteria for oncologic conditions are based on the National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21) and the Medicare Benefit Manual, Chapter 15.

For patients initiating therapy:

1.All diagnoses, with the exception of 2d (preoperative use in patients scheduled for elective non-cardiac, nonvascular surgery), must have documented Hemoglobin (HGB) levels of less than 10 g/dl (or hematocrit less than 30%) within the 30 days prior to initiation of therapy

AND

2.Must meet all of the listed criteria below for each specific diagnosis:

a.Treatment of Anemia in Chronic Kidney Disease (CKD)

- i.If the patient is undergoing dialysis, these agents will be covered as a Part B bundle payment
- ii.For patients not on dialysis: Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
- b.Treatment of anemia secondary to chemotherapy in patients with cancer:
 - i.Documentation that anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia (other cancer types are not covered – see exclusion criteria)
- c.Anemia associated with zidovudine-treated HIV-infection patients
 - i.Documented current (within last three months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
 - ii.Zidovudine dose is less than or equal to 4200mg/week
- d.Preoperative use in patients scheduled for elective noncardiac and nonvascular surgery, all of the following criteria must be met:
 - i.Documentation that the patient will be undergoing hip or knee surgery
 - ii.Documentation that anemia is due to chronic disease
 - iii.Member has preoperative HGB between 10 and 13 g/dL
 - iv.The surgery has a high-risk for perioperative blood loss (for example, expected to lose more than two units of blood)
 - v.Patient is unwilling or unable to donate autologous blood pre-operatively
- e.Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis:
 - i.Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
 - ii.Must have documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL
- g.Mircera only: For the treatment of pediatric patients 5 to 17 years of age who are on hemodialysis and converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
 - i.Documented hemodialysis for at least eight weeks
 - ii.Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
 - iii.Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

For patients established on therapy (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):

- 1.Documentation of continued medical necessity (such as ongoing chronic kidney disease)
- 2.Documented HGB levels of less than or equal to 12 g/dl within previous 30 days

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be for one year. For use during chemotherapy, therapy should be discontinued eight weeks following the final dose of myelosuppressive chemotherapy (subject to audit).

OTHER CRITERIA

N/A

EXON-SKIPPING THERAPIES FOR DUCHENNE MUSCULAR DYSTROPHY_MEDICAL BENEFIT

MEDICATION(S)

AMONDYS-45, EXONDYS-51, VILTEPSO, VYONDYS-53

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

N/A

OTHER CRITERIA

Exon-skipping therapies for Duchene Muscular Dystrophy are not considered medically necessary and will not be covered due to the lack of clinical evidence of improved outcomes and safety.

FERTILITY AND RELATED MEDICATIONS

MEDICATION(S)

CETRORELIX ACETATE, CETROTIDE, CHORIONIC GONAD 10,000 UNIT VL, CHORIONIC GONAD 12,000 UNIT VL, CHORIONIC GONAD 6,000 UNIT VL, FOLLISTIM AQ, FYREMADEL, GANIRELIX ACETATE, GONAL-F, GONAL-F RFF, GONAL-F RFF REDI-JECT, MENOPUR, NOVAREL, OVIDREL, PREGNYL

COVERED USES

N/A

EXCLUSION CRITERIA

1. Hypogonadism, unrelated to infertility
2. Cryptorchidism

REQUIRED MEDICAL INFORMATION

1. For fertility preservation, preferred gonadotropins and Lupron® may be covered if the patient's benefit covers fertility preservation, meeting one of the following scenarios (a or b):
 - a. The patient's benefit covers fertility preservation ONLY when due to treatment for cancer and the following criteria are met:
 - i. The gonadotropin will be used for retrieval and storage of eggs and/or sperm
 - ii. The patient will be undergoing treatment for cancer that is expected to cause irreversible infertility as recommended by evidence-based guidelines such as the National Comprehensive Cancer Network (NCCN),
 - b. The patient's benefit covers fertility preservation for any reason (such as egg/sperm storage)
2. For treatment of infertility, preferred gonadotropins and Lupron® may be covered if the patient's benefit covers the planned infertility treatment [e.g., intrauterine insemination (IUI) vs. in vitro fertilization (IVF)].
3. Non-preferred therapies may be covered when criteria 1 or 2 above are met and subject to the following criteria:
 - a. For Gonal-F®: documented inadequate response, intolerance, or contraindication to Follistim AQ®
 - b. For Ovidrel®: documented inadequate response, intolerance, or contraindication to Novarel®, Pregnyl®, or generic chorionic gonadotropin
 - c. For Cetrotide®: documented inadequate response, intolerance, or contraindication to Ganirelix®

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization will be approved for one year

OTHER CRITERIA

N/A

GIVLAARI_MEDICAL BENEFIT

MEDICATION(S)

GIVLAARI

COVERED USES

N/A

EXCLUSION CRITERIA

Use post liver transplant

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria must be met:

1. Confirmed diagnosis of acute hepatic porphyria [i.e., acute intermittent porphyria, hereditary corproporhyria, variegate porphyria, aminolevulinic acid (ALA) dehydratase deficient porphyria]

AND

2. One of the following:

a. Active disease defined as two (2) documented porphyria attacks within the past six (6) months which required either hospitalization, urgent care visit, or intravenous hemin administration, or

b. Patient is currently receiving treatment with prophylactic hemin to prevent porphyria attacks

3. Documentation that patient will not receive concomitant prophylactic hemin treatment while on therapy with givosiran therapy

4. Documentation that patient's dosing is in accordance with FDA labeling (patient's current weight must be included in documentation) and is subject to audit

Reauthorization requires documentation of one of the following:

1. Reduction in the number or severity of porphyria attacks

2. Reduction in number of hospitalizations due to acute porphyria attacks

3. Decreased hemin administration from baseline

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist

COVERAGE DURATION

Initial authorization will be approved for 6 months.

Reauthorization will be approved for 1 year.

OTHER CRITERIA

N/A

GONADOTROPIN RELEASING HORMONE AGONISTS _MEDICARE PART B

MEDICATION(S)

CAMCEVI, ELIGARD, FENSOLVI, LEUPROLIDE DEPOT, LUPRON DEPOT, LUPRON DEPOT-PED, SUPPRELIN LA, TRELSTAR, TRIPTODUR, VANTAS, ZOLADEX

COVERED USES

N/A

EXCLUSION CRITERIA

Treatment of male infertility

REQUIRED MEDICAL INFORMATION

1.For initiation of therapy with the requested agent (new starts), must meet the indication-specific criteria outlined below:

a.For oncological indications: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

b.For anemia associated with uterine leiomyomata (fibroids)

i.Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone AND

ii.Documentation that Lupron® will be used in combination with iron supplementation

c.For uterine leiomyomata (fibroids)

i.Documentation that surgical removal of fibroids is planned within four months

d.For endometriosis: Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders)

e.For central precocious puberty, all of the following criteria must be met:

i.Documentation of a history of early onset of secondary sexual characteristics (age eight years and under for females or nine years and under for males),

AND

ii.Confirmation of diagnosis by one of the following:

1.Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [e.g., stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)]

2.Pubertal level of basal LH levels (0.3 IU/L or greater)

3.Bone age advanced one (1) year beyond the chronological age

f.For gender-affirming services:

i.Prescribed by or in consultation with an endocrinologist

ii.Demonstration that puberty has progressed to a minimum of Tanner Stage 2

g.For Endometrial thinning/dysfunctional uterine bleeding: Documentation for use prior to endometrial

ablation

2. For patients established on the requested therapy (within the previous year), must meet indication-specific criteria below :

- a. For oncological indications, gender-affirming services : documentation of clinical response to therapy
- b. For anemia associated with uterine leiomyomata (fibroids): Documentation that the patient has not received more than three months of therapy
- c. For uterine leiomyomata (fibroids): Documentation that the patient has not received more than four months of therapy
- d. For central precocious puberty, all of the following criteria must be met:
 - i. Documentation of clinical response to treatment such as pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level, and
 - ii. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression.
 - iii. Discontinuation of leuprolide should be considered before age 11 years for females and age 12 years for males. However, treatment discontinued at the appropriate age of onset of puberty should be at discretion of the treating provider.
- e. For endometriosis:
 - i. For Lupron®:
 1. Requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g., norethindrone) to help prevent bone mineral density loss.
 2. Documentation that the patient has not received more than 12 months of therapy
 - ii. Zoladex® continuation of therapy is not recommended. Treatment is only recommended for up to six months for endometriosis
- f. For Endometrial thinning/dysfunctional uterine bleeding: Documentation that patient has not had more than two months of therapy

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Anemia from fibroids: Authorization will be approved for up to three months (NO reauthorization)

Uterine leiomyomata (fibroids): Authorization will be approved for four months. No reauthorization

Endometriosis: For Lupron®– authorization/reauthorization will be approved for up to six months (total of 12 months). For Zoladex® - initial authorization for up to six months and no reauthorization

CPP and gender-affirming services: Authorization/reauthorization will be approved for up to one year

Endometrial Thinning/Dysfunctional Uterine Bleeding: Initial authorization for two months. No

reauthorization.

Oncological Indications: Authorization/reauthorization will be approved for one year

OTHER CRITERIA

N/A

HEMGENIX

MEDICATION(S)

HEMGENIX

COVERED USES

N/A

EXCLUSION CRITERIA

- Current or prior presence of factor IX inhibitors
- HIV not controlled with antiviral therapy (CD4+ counts equal to 200/ μ L or by a viral load of greater than 200 copies/mL)
- Active hepatitis B or C infection
- Evidence of advanced liver fibrosis (Fibroscan score of 9 kPA or greater)
- ALT, AST, total bilirubin, alkaline phosphatase, or creatinine greater than two times the upper limit of normal
- Previous treatment with gene therapy for the same indication

REQUIRED MEDICAL INFORMATION

Hemgenix® may be approved when all the following criteria are met:

1. Diagnosis of severe or moderately severe hemophilia B, defined by Factor IX level less than 2 IU/dL or less than or equal to 2% of normal
2. Patient is male
3. One of the following:
 - a. Patient is currently on a stable dose of factor IX prophylaxis (has been receiving prophylaxis for 2 months or more) with greater than 150 exposure days of factor IX prophylaxis
 - b. Current or historical life-threatening hemorrhage
 - c. Documentation of repeated, serious spontaneous bleeding episodes
4. Hemgenix® will be administered by or in consultation with a Hemophilia Treatment Center (HTC)

AGE RESTRICTION

May be approved for patients aged 18 years and older.

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a hematologist.

COVERAGE DURATION

Authorization will be limited to one treatment course per lifetime.

OTHER CRITERIA

N/A

HEMLIBRA MEDICAL BENEFIT

MEDICATION(S)

HEMLIBRA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- AND
2. Diagnosis of hemophilia A (congenital factor VIII deficiency) and documentation of ANY of the following:
 - a. Factor VIII inhibitors (defined as at least 5 Bethesda units per milliliter)
 - b. Severe hemophilia (defined as pre-treatment factor VIII level less than 1%)
 - c. Moderate hemophilia (defined as pre-treatment factor VIII level of 1% to less than 5%) or mild hemophilia (defined as pre-treatment factor VIII level of 5% to less than 40%) with:
 - i. One or more spontaneous episodes of bleeding into the central nervous system, large joints (ankles, knees, hips, elbows, shoulders) or other serious, life-threatening bleed

When the above criteria are met, Hemlibra® (emicizumab-kxwh) will be approved for a loading dose of 3 mg/kg once weekly for four weeks, followed by any of the three maintenance dosing regimens below:

- 1.5 mg/kg once weekly
- 3 mg/kg every two weeks
- 6 mg/kg every four weeks

Reauthorization criteria: Documentation of positive clinical response to emicizumab therapy (e.g., reduction in the number/severity of bleeds)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

To be prescribed by, or in consultation with a hematologist.

COVERAGE DURATION

Initial authorization: six months

Reauthorization: Authorization will be approved until no longer eligible with the plan, subject to formulary

and/or benefit changes.

OTHER CRITERIA

N/A

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH) AGENTS_MEDICARE PART B

MEDICATION(S)

EVKKEEZA

COVERED USES

N/A

EXCLUSION CRITERIA

1. Concomitant use of evinacumab-dgnb and lometapide (Juxtapid®)
2. Current pregnancy
3. Diagnosis of Heterozygous familial hypercholesterolemia or other hyperlipidemia disorders

REQUIRED MEDICAL INFORMATION

All of the following must be met:

1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by either genetic or clinical confirmation, as outlined below:
 - a. Genetic confirmation: biallelic functional mutations in the low density lipoprotein receptor (LDLR), apolipoprotein B (apo B), or proprotein convertase subtilisin/kexin type 9 (PCSK9) genes
 - b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL and one of the following:
 - i. Presence of xanthomas before the age of 10 years, or
 - ii. Untreated total cholesterol level greater than 250 mg/dL in both parents
2. Current use of all of the following therapies:
 - a. High-intensity statin therapy, defined as atorvastatin 80mg daily or rosuvastatin 40mg daily, unless contraindicated or documented statin intolerance
 - b. Ezetimibe, unless contraindicated or prior intolerance
 - c. PCSK-9 inhibitor (e.g., evolocumab), unless contraindicated or prior intolerance
3. Documentation of LDL cholesterol levels greater than 100 mg/dL despite at least six (6) months of use of the therapies outlined above

Initial reauthorization requires documentation of at least a 30% reduction in LDL cholesterol levels from pre-treatment levels

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

OTHER CRITERIA

N/A

IL-5 INHIBITORS _ MEDICARE PART B

MEDICATION(S)

CINQAIR, FASENRA, FASENRA PEN, NUCALA

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet indication-specific criteria below:

a. For eosinophilic asthma:

i. Documentation of eosinophilic asthma by one of the following:

1. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months, or
2. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids, or
3. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist) and has been compliant to therapy in the past three months (this may be verified by pharmacy claims information)

ii. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:

1. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5, or
2. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months, or
3. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit.

b. For Eosinophilic Granulomatosis with Polyangiitis (EGPA), mepolizumab (Nucala®) may be covered if all of the following criteria are met:

i. Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

ii. History or presence of asthma

iii. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter

iv. Documentation of one of the following:

1. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent), OR

2. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

c. For Hyperesoinophilic Syndrome (HES) mepolizumab (Nucala®) may be covered if the following criteria are met:

- i. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
- ii. Blood eosinophil count of at least 1,000 cells/microliter for at least six months
- iii. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
 1. Chronic or episodic oral corticosteroids
 2. Immunosuppressive therapy
 3. Cytotoxic therapy
- iv. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

d. For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), mepolizumab (Nucala®) may be covered if the following criteria are met:

- i. Evidence of nasal polyposis by direct examination, endoscopy, or sinus CT scan
- ii. Documentation of one of the following:
 1. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
 2. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
- iii. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
- iv. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

2. For patients established on the requested therapy within the previous year: documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

AGE RESTRICTION

Nucala®: May be covered for patients six years of age or older for eosinophilic asthma, 18 years of age and older for EGPA and CRSwNP and 12 years of age and older for HES

Cinqair®: May be covered for patients for 18 years of age or older

Fasenra®: May be covered for patients for 12 years of age or older

PRESCRIBER RESTRICTION

For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

For Eosinophilic Granulomatosis with Polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist

For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.

For chronic rhinosinusitis with nasal polyposis: must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist

COVERAGE DURATION

For EGPA and HES: Initial authorization and reauthorization will be approved for one year.

For asthma: Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

For chronic rhinosinusitis with nasal polyposis: Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

IMMUNE GAMMA GLOBULIN (IGG)

MEDICATION(S)

ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial Authorization for ALL indications:

1. The medical diagnosis is an FDA approved indication or is listed as a covered medical condition below and any indication specific criteria in the policy is met

AND

2. Requested dosage, frequency and length of therapy are supported by FDA-approved labeling, accepted compendia and/ or evidence-based practice guidelines. If request is for a non-standard dose, frequency or length, medical rationale should be provided and exceptions will be considered on a case by case basis.

Dosing is subject to audit.

Re-Authorization for ALL indications:

1. Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

Indication-Specific Requirements:

Primary immune deficiency disorders such as agammaglobulinemia, hypogammaglobulinemia (common variable immunodeficiency), Hyper-IgM (X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome

1. The patient has one of the following:

a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy

b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein

c. The patient has an absence of B lymphocytes

d. The patient meets all of the following:

i. One of the following:

1) The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses

(e.g., IgG1, IgG2, IgG3, or IgG4) more than two standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period

2) The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses

3) The patient has hypogammaglobulinemia (defined as total IgG less than 700 mg/dL OR more than two SDs below mean for the patient's age at baseline prior to immune globulin therapy)

ii. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (such as inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both)

iii. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (such as recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics)

Reauthorization:

1. Documentation that treatment has been effective in reducing the number or severity of clinical infections

Prevention of infections in patients with B-cell chronic lymphocytic leukemia (CLL):

1. Documented pre-treatment endogenous IgG less than 700 mg/dL OR more than two standard deviations below mean for the patient's age

OR

2. History of recurrent, severe bacterial infections requiring antibiotics and/or hospitalization

Kawasaki Disease:

1. Documentation that use is for acute treatment given in conjunction with aspirin and within 10 days of the onset of symptoms

Idiopathic or Immune Thrombocytopenic Purpura (ITP):

(Platelet counts expressed per microliter and should be obtained within the past 30 days)

For children with ITP:

1. Documentation of one of the following:

a. Platelet count less than 20,000 and significant mucous membrane bleeding

b. Platelet count less than 10,000 and minor purpura

c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

Pregnant Women with ITP:

1. Documentation of one of the following:

a. Platelet count is less than 100,000

b. Past history of splenectomy

c. Past history of delivered infant with autoimmune thrombocytopenia

Adult Patients with ITP:

1. Documentation of one of the following:
 - a. Platelet count of less than 30,000
 - b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding
 - c. To defer or avoid splenectomy
 - d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)
2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated

Dermatomyositis and polymyositis:

1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
AND
2. Documented trial, failure, intolerance or contraindication to immunosuppressant therapy (e.g., methotrexate, azathioprine, cyclosporine, 6-mercaptopurine, chlorambucil, cyclophosphamide)
AND
3. Documentation of severe symptoms/disability despite previous therapy with above agents

Reauthorization: Documented response to therapy

Chronic inflammatory demyelinating polyneuropathy (CIDP):

1. Documentation of severe disability
AND
2. One of the following:
 - a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
 - b. Documentation of pure motor CIDP

Autoimmune Hemolytic Anemia:

1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (such as prednisone or methylprednisolone)
AND
2. Documented trial, failure, intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)

Guillain-Barre Syndrome:

1. Documentation that symptom onset is within two weeks or symptoms are severe (such as being unable to ambulate independently)

AND

2. Documented trial, failure, intolerance or contraindication to plasma exchange

Multifocal motor neuropathy:

1. Confirmed diagnosis: motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities

AND

2. Documentation of severe disease/disability

Multiple Sclerosis:

1. Documentation of relapsing/remitting disease

AND

2. Documented trial, failure, intolerance or contraindication to at least two conventional therapies (such as glatiramer, interferon beta, dimethyl fumarate)

Myasthenia Gravis:

Myasthenic exacerbation:

1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:

a. Difficulty swallowing

b. Acute respiratory failure

c. Major functional disability responsible for the discontinuation of physical activity

Refractory disease:

1. Documentation that patient has severely impaired function due to myasthenia gravis

AND

2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies:

a. Acetylcholinesterase inhibitors (such as pyridostigmine)

b. Corticosteroids (such as prednisone, methylprednisolone)

c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate)

d. Plasma exchange

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:

1. Documentation of one of the following:

a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)

OR

b. Documentation that patient has an IgG less than 400 mg/dL with a history of recurrent infections

Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis

1. Documentation of biopsy proven disease

AND

2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS):

1. Clinical documentation must be provided detailing patient's primary symptom complex along with baseline clinical testing(s) using validated instrument(s)

AND

2. A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex. For example, treatments may include appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, or short-course antibiotic therapy). These trials may be done concurrently.

Reauthorization in PANDAS/PANS:

1. Documentation that a reevaluation at three months post treatment have been performed by an appropriate specialist

AND

2. Documentation of objective clinically meaningful improvement posttreatment as defined by an improvement in the clinical testing with a validated instrument

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)

1. Documentation of severe residual deficits following an initial attack, to prevent further disability (for example, to preserve vision in patients with residual monocular blindness after an initial attack)

OR

2. As maintenance treatment for patients who have experienced at least one relapse following an initial attack

Reauthorization for MOGAD: Documented positive response to therapy as demonstrated by recovery of function from previous attack or reduction in frequency or severity of attacks.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an appropriate specialist (such as a neurologist for multiple sclerosis, immunologist, hematologist or infections disease expert for primary immunodeficiency, neurologist, psychiatrist, or rheumatologist for PANDAS/PANS)

COVERAGE DURATION

Generally, initial authorization is up to six months subject to criteria and reauthorization is up to one year subject to criteria.

OTHER CRITERIA

N/A

INJECTABLE ANTI-CANCER MEDICATIONS _ MEDICARE PART B

MEDICATION(S)

ABRAXANE, ADCETRIS, ALIQOPA, ALKERAN 50 MG VIAL, ALYMSYS, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BLENREP, BLINCYTO, BORTEZOMIB, COSELA, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, ELAHERE, ELZONRIS, EMLICITI, ENHERTU, ERBITUX, EVOMELA, FASLODEX, FOLOTYN, FULVESTRANT, FYARRO, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMJUDO, IMLYGIC, ISTODAX, IXEMPRA, JELMYTO, JEMPERLI, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KIMMTRAK, KYPROLIS, LIBTAYO, LUMOXITI, LUNSUMIO, LUTATHERA, MARGENZA, MELPHALAN HCL, MONJUVI, MVASI, MYLOTARG, NELARABINE, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, OPDUALAG, PACLITAXEL PROTEIN-BOUND, PADCEV, PEDMARK, PEPAXTO, PERJETA, PHESGO, PLUVICTO, POLIVY, PORTRAZZA, POTELIGEO, PRALATREXATE, ROMIDEPSIN, RYBREVANT, RYLAZE, SARCLISA, SYNRIPO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TIVDAK, TORISEL, TRAZIMERA, TREANDA, TRODELVY, VECTIBIX, VEGZELMA, VELCADE, VIDAZA, VIVIMUSTA, VYXEOS, XOFIGO, YERVOY, YONDELIS, ZALTRAP, ZEPZELCA, ZIRABEV, ZYNLONTA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts):

- a. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
- b. For non-preferred trastuzumab products: Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Ogivri® (trastuzumab-dkst) and Kanjinti® (trastuzumab-anns)
- c. For non-preferred bevacizumab products: Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb)

2. For patients established on the requested product (within the previous year): documentation of adequate response to the medication must be provided.

For bevacizumab given via intravitreal injection: See payment policy 97.0 Compound Drugs Administered in the Physician's Office

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with an oncologist

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA

N/A

INTERLEUKIN-1 INHIBITORS_ MEDICARE PART B

MEDICATION(S)

ILARIS

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet the indication-specific criteria outlined below:
 - a. For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by both of the following:
 - i. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1), AND
 - ii. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold
 - b. For Familial Mediterranean Fever (FMF), and all the following:
 - i. Documented trial and failure, contraindication or intolerance to colchicine, AND
 - ii. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints).
 - c. Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by:
 - i. Laboratory evidence of genetic mutation MVK (mevalonate kinase), AND
 - ii. Classic symptoms associated with HIDs (abdominal pain, lymphadenopathy, aphthous ulcers).
 - d. Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by:
 - i. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family), AND
 - ii. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations).
 - e. Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease:
 - i. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy

(e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), AND

ii. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

2. For patients established on therapy (within the previous year): Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)

AGE RESTRICTION

Ilaris® may be covered for patients aged four years of age and older in patients with CAPS (which includes FCAS, MWS), Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF

Ilaris® may be covered for patients aged two years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis and Adult Onset Still's Disease (AOSD)

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

KORSUVA MEDICARE PART B

MEDICATION(S)

KORSUVA

COVERED USES

N/A

EXCLUSION CRITERIA

Use with peritoneal dialysis

REQUIRED MEDICAL INFORMATION

For initiation of therapy (new starts), all the following must be met:

1. Diagnosis of moderate to severe pruritis associated with chronic kidney disease. Moderate to severe pruritis is defined as a score of 4 or higher on the Worst Itching Intensity numerical scale (WI-NRS) or pruritis that is severe enough to impair quality of life
2. Undergoing hemodialysis for at least three months
3. Prescriber attestation that the following have been optimized:
 - a. Dialysis
 - b. Laboratory abnormalities such as parathyroid, phosphate, magnesium
 - c. Use of topical emollients
4. Documented inadequate response to at least two weeks trial of an oral antihistamine, or intolerance/contraindication to antihistamine therapy
5. Documented inadequate response to at least two weeks trial of pregabalin or gabapentin, or intolerance/contraindication to both pregabalin and gabapentin
6. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy (within the previous year), all the following must be met:

1. Undergoing hemodialysis
2. Documentation of positive response to therapy, defined as an improvement of at least three points on the WI-NRS from baseline or improvement in quality of life
3. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

May be approved for patients aged eighteen (18) years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a nephrologist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

KRYSTEXXA MEDICAL BENEFIT

MEDICATION(S)

KRYSTEXXA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial therapy, all the following criteria must be met:

1. Diagnosis of chronic gout
2. Documentation of inadequate response, intolerance or contraindication to both of the following at maximum medically appropriate doses:
 - a. Xanthine oxidase inhibitor (such as allopurinol)
 - b. Uricosuric agent (such as probenecid).

Note: Inadequate response is defined as inability to achieve uric acid levels of less than 6 mg/dL after at least three months of continuous therapy.

3. Documentation of symptomatic gout, as defined by one or more of the following, despite therapies outlined in criterion 2 above:
 - a. At least two gout flares per year
 - b. Non-resolving tophi

Reauthorization requires documentation of a decreased uric acid level from baseline

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for six months.

OTHER CRITERIA

N/A

LEMTRADA_MEDICARE PART B

MEDICATION(S)

LEMTRADA

COVERED USES

N/A

EXCLUSION CRITERIA

1. In combination with other disease modifying therapy indicated for the treatment of multiple sclerosis

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), all the following criteria must be met:

a. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease, AND

b. Documentation of active disease (such as patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to ocrelizumab (Ocrevus®). An adequate trial is defined as at least six months, AND

c. Documentation of active disease after an adequate trial of at least one of the following additional disease modifying therapies unless all are contraindicated. An adequate trial is defined as at least six months of continuous therapy. Discontinuation of therapy due to drug intolerance will not be considered as an adequate trial

i. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®) or interferon-beta 1b (Betaseron®)

ii. Generic dimethyl fumarate

iii. Glatiramer acetate (Copaxone®)

iv. Natalizumab (Tysabri®)

v. Teriflunomide (Aubagio®)

vi. Fingolimod (Gilenya®)

vii. Diroximel fumarate (Vumerity®)

viii. Ozanimod hydrochloride (Zeposia®)

ix. Siponimod (Mayzent®)

For patients established on therapy (within the previous year), all the following must be met:

1. Documentation of positive clinical response to therapy

2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION

Authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

OTHER CRITERIA

N/A

LUXTURNA MEDICAL BENEFIT

MEDICATION(S)

LUXTURNA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

All the following must be met:

1. Confirmed biallelic RPE65 gene mutation, and
2. Has not previously had the intended treatment eye treated with gene therapy for retinal dystrophy RPE65 mutations, and
3. Documentation by an ophthalmologist within the previous six months of BOTH of the following:
 - a. Presence of sufficient viable retinal cells in the intended treatment eye as evidenced by an area of retina within the posterior pole of more than 100 micrometer thickness shown on optical coherence tomography, and
 - b. The member has remaining light perception in the intended treatment eye

AGE RESTRICTION

Approved for 12 months of age and older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an ophthalmologist from a certified Luxturna® administration site

COVERAGE DURATION

Authorization is limited to one treatment course per eye per lifetime. Approval duration will be for six months.

OTHER CRITERIA

N/A

MEDICAL NUTRITION _MEDICARE PART B

MEDICATION(S)

GLYTACTIN 20PE BETTERMILK LITE, GLYTACTIN RESTORE 10 PE, GLYTACTIN RESTORE 10 PE LITE, GLYTACTIN RESTORE 5 PE, GLYTACTIN RTD 10 PE, GLYTACTIN RTD 15 PE, GLYTACTIN RTD LITE 15, GLYTACTIN SWIRL 15 PE, HOMACTIN AA PLUS 20 PE, RELIZORB, TYLACTIN RESTORE 10 PE, TYLACTIN RESTORE 5 PE, VILACTIN AA PLUS 20 PE

COVERED USES

N/A

EXCLUSION CRITERIA

- Members with a functioning gastrointestinal tract whose need for enteral nutrition due to anorexia or nausea associated with mood disorder or end-stage disease
- Food thickeners, baby food, and other regular grocery products that can be blenderized and used with the enteral system
- Formulas used to replace fluids and electrolytes

REQUIRED MEDICAL INFORMATION

1. Documentation of a medical condition that prevents food from reaching the digestive tract (e.g. head and neck cancer with reconstructive surgery, central nervous system disease that interferes with neuromuscular mechanisms of ingestion) or disease of the small bowel that impairs digestion and/or absorption of an oral diet.

AND

2. Documentation that the condition is of long and indefinite duration (typically 90 days or longer) as deemed by the judgment of the attending provider or substantiated in the medical records

AND

3. The gastrointestinal tract is functional and can be accessed via tube to allow for adequate nutrient absorption.

AND

4. Documentation that enteral nutrition is the sole/primary source of nutrition (i.e., enteral nutrition is required in order to maintain adequate weight and strength)

Reauthorization:

The assessment and treatment plan must demonstrate that adequate nutrition (at least 75% of required intake) is not possible by dietary adjustment and/or oral supplementation.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

MEDICALLY INFUSED THERAPEUTIC IMMUNOMODULATORS (TIMS) _MEDICARE PART B

MEDICATION(S)

ACTEMRA 200 MG/10 ML VIAL, ACTEMRA 400 MG/20 ML VIAL, ACTEMRA 80 MG/4 ML VIAL, AVSOLA, CIMZIA 200 MG VIAL KIT, ENTYVIO, ILUMYA, INFLECTRA, INFLIXIMAB, ORENCIA 250 MG VIAL, REMICADE, RENFLEXIS, SIMPONI ARIA, SKYRIZI 600 MG/10 ML VIAL, STELARA 130 MG/26 ML VIAL

COVERED USES

N/A

EXCLUSION CRITERIA

Combination therapy with another therapeutic immunomodulator (TIM) agent or apremilast (Otezla®).

REQUIRED MEDICAL INFORMATION

1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (such as the American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.)

AND

2. The requested agent will not be given concurrently with another therapeutic immunomodulator (TIMs) agent or apremilast (Otezla®)

AND

3. One of the following:

a. For patients already established on the requested TIMs agent within the previous year: Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

b. Patients not established on the requested TIMs agent (new starts), must meet ALL of the following indication-specific criteria:

i. Requests for non-preferred infliximab products (Remicade® and Avsola®) will require documentation of failure, intolerance or contraindication to the preferred infliximab products, Inflectra® and Renflexis®, in addition the indication-specific criteria below. Accepted contraindications include: contraindications listed in the package insert or a documented allergic reaction to an ingredient found only in the preferred biosimilar product(s).

ii. For moderate to severe Ulcerative Colitis:

1. Preferred infliximab products (Inflectra® and Renflexis®) or vedolizumab (Entyvio®) may be covered

2. For non-preferred agents: documentation of failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®) or vedolizumab (Entyvio®)

iii. For moderate to severe Crohn's Disease:

1. Preferred infliximab products (Inflectra® and Renflexis®) may be covered

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®) or vedolizumab (Entyvio®)

iv.For Rheumatoid Arthritis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

v.For moderate to severe Plaque Psoriasis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vi.For Psoriatic Arthritis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vi.For Ankylosing Spondylitis:

1.Preferred infliximab products (Inflectra® and Renflexis®) may be covered

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vii.For giant cell arteritis: Tocilizumab (Actemra®) may be approved with documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)

viii.For systemic sclerosis (SSc-ILD), tocilizumab (Actemra®) may be covered if the patient has interstitial lung disease, as evidenced by high-resolution computed tomography (HRCT)

ix.For immune checkpoint inhibitor related diarrhea/colitis, a preferred infliximab products (Inflectra® and Renflexis®) may be covered if the following criteria are met:

1.Documentation of severe diarrhea/colitis (G3-4)

2.Documentation of inadequate response to a 1-2 day trial of intravenous methylprednisolone

AGE RESTRICTION

Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION

For patients not established on the requested TIMs agent: Must be prescribed by, or in consultation with, a specialist for the respective indication, such as:

- Rheumatoid arthritis, ankylosing spondylitis: must be prescribed by, or in consultation with, a rheumatologist

- Psoriasis: must be prescribed by, or in consultation with, a dermatologist

- Psoriatic arthritis: must be prescribed by, or in consultation with, a dermatologist or rheumatologist

- Inflammatory Bowel Disease: must be prescribed by, or in consultation with, a gastroenterologist
- Giant Cell Arteritis: must be prescribed by, or in consultation with, a rheumatologist or neurologist
- Systemic sclerosis-associated interstitial lung disease: must be prescribed by, or in consultation with, a pulmonologist or rheumatologist
- Immune checkpoint inhibitor related diarrhea/colitis: must be prescribed by, or in consultation with, an oncologist or gastroenterologist

COVERAGE DURATION

For immune checkpoint inhibitor related diarrhea/colitis: Authorization will be approved for three months

For all other indications: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

MEDICATIONS FOR RARE INDICATIONS

MEDICATION(S)

GAMIFANT, NULIBRY

COVERED USES

N/A

EXCLUSION CRITERIA

For Galafold® only – combination therapy with enzyme replacement therapy [such as agalsidase beta (Fabrazyme®)] for the treatment of Fabry disease

REQUIRED MEDICAL INFORMATION

Both of the following must be met:

1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted
 - a. For Nulibry®: Diagnosis of molybdenum cofactor deficiency (MoCD) Type A confirmed by a mutation in the MOCS1 gene OR suspected molybdenum cofactor deficiency (MoCD) Type A

AND

2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information

AND

3. For Pheburane Pellet (sodium phenylbutyrate): Documented trial and failure or intolerance to formulary generic sodium phenylbutyrate powder

REAUTHORIZATION CRITERIA:

The following must be met:

1. Documentation of successful response to therapy

AND

2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information

AND

3. For Nulibry®: Genetic testing to confirm mutation in the MOCS1 gene (Nulibry® should be discontinued if the MoCD Type A diagnosis is not confirmed by genetic testing)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with a specialist in the respective disease state.

COVERAGE DURATION

For Daybue®: Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

For Nulibry®: Initial authorization will be approved for three months. Reauthorization will be approved for 12 months.

For all other medications: Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

OPHTHALMIC VEGF INHIBITORS _ MEDICARE PART B

MEDICATION(S)

BEOVU, CIMERLI, LUCENTIS, SUSVIMO, VABYSMO

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy with the requested medication (new start): Must have one of the following diagnoses and meet any required criteria:
 - a. Neovascular (wet) age-related macular degeneration (AMD):
 - i. For faricimab (Vabysmo®) and brolucizumab (Beovu®): Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient
 - ii. For ranibizumab (Lucentis): Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
 1. bevacizumab
 2. aflibercept (Eylea®)
 3. ranibizumab-nuna (Byooviz®)
 - iii. For ranibizumab implant (Susvimo®):
 1. Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient AND
 2. Documentation of previous response to at least two intravitreal injections of ranibizumab (Lucentis®) or ranibizumab-nuna (Byooviz®) AND
 3. Documentation that increased risk of endophthalmitis associated with ranibizumab (Susvimo®) has been discussed with the patient

b. Diabetic macular edema or Diabetic retinopathy:

i. For faricimab (Vabysmo®) and brolucizumab (Beovu®): Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member

ii. For ranibizumab (Lucentis): Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:

1. bevacizumab
2. aflibercept (Eylea®)
3. ranibizumab-nuna (Byooviz®)

c. Macular edema following retinal vein occlusion:

i. For ranibizumab (Lucentis®): Documentation that ALL the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:

1. bevacizumab
2. aflibercept (Eylea®)
3. ranibizumab-nuna (Byooviz®)

d. Myopic Choroidal Neovascularization (mCNV):

i. For ranibizumab (Lucentis®): Documentation that ranibizumab-nuna (Byooviz®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy with ranibizumab-nuna (Byooviz®) is not appropriate for the patient

2. For patients established on therapy with the requested agent (within the previous year): Documentation of positive response to therapy (such as stabilization or improvement in vision)

QUANTITY LIMITS:

Approval may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines and are subject to medical claims audits.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed and administered by an ophthalmologist or retinal specialist

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

OSTEOANABOLIC AGENTS

MEDICATION(S)

EVENITY, EVENITY (2 SYRINGES)

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent use with another osteoanabolic agent (such as Evenity®, Forteo®, and Tymlos®)

For Evenity® only: Myocardial infarction or stroke within the preceding year, hypocalcemia

REQUIRED MEDICAL INFORMATION

For the treatment or prevention of osteoporosis

1. Must meet ONE of the following criteria (a-e):

a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures

b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -3.0

c. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 to -3.0 and high risk for fracture, defined as one of the following:

i. Age more than 80 years

ii. Chronic glucocorticoid use

iii. Documented increased fall risk

d. Patient has a spine or hip BMD T-score less than or equal to -2.5 to -3.0 and one of the following:

i. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy

ii. Documented contraindication or intolerance to therapy with all the following: 1. denosumab, 2. oral bisphosphonate (such as alendronate), and 3. IV bisphosphonate therapy (such as zoledronic acid)

e. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:

i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%

ii. One of the following:

1. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy

2. Documented contraindication or intolerance to therapy with all the following:

a. Denosumab

b. Oral bisphosphonate (such as alendronate)

c. IV bisphosphonate therapy (such as zoledronic acid).

2. For patients requesting teriparatide (Forteo®), brand or generic:

a. Documentation of trial and failure or intolerance to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos®.

AND

b. Total duration of treatment with any parathyroid analogue (teriparatide, Forteo®, Tymlos®) has not exceeded two years.

For authorization for teriparatide or brand Forteo® use exceeding two years in a lifetime, must meet both of the following criteria:

1. Documentation that previous treatment with teriparatide showed clinical improvement, defined as absence/decrease in frequency of new fragility fracture or stable/increased BMD T-score while on teriparatide

2. One of the following:

a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide:

i. BMD T-score continues to be less than or equal to -3.0

ii. New vertebral or fragility fracture

b. Documentation of worsening disease, defined as one of the following:

i. A repeat BMD after discontinuation of therapy demonstrates a decline in BMD

ii. New onset fragility fracture after discontinuation

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an endocrinologist or rheumatologist

COVERAGE DURATION

For Forteo®: Initial authorization may be approved for up to two years.

For use beyond two years, may be approved for up to one year provided that cumulative duration of parathyroid analogue therapy (teriparatide, Forteo®, Tymlos®) does not exceed three years in a lifetime, including both previous and planned future doses.

For Tymlos®: May be approved for up to two years, ensuring the cumulative duration of parathyroid analogue therapy (teriparatide, Forteo®, Tymlos®) does not exceed two years in a lifetime.

For Evenity®: May be approved for up to one year, ensuring the total duration of Evenity® therapy does not exceed one year of total therapy duration.

OTHER CRITERIA

N/A

OXLUMO_MEDICARE PART B

MEDICATION(S)

OXLUMO

COVERED USES

N/A

EXCLUSION CRITERIA

1. Patients with a history of liver transplant
2. Patients with an estimated glomerular filtration rate (eGFR) less than 30

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), all the following criteria must be met:
 - a. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1), confirmed by one of the following:
 - i. Genetic testing demonstrating mutation in the alanine: glyoxylate aminotransferase (AGXT) gene
 - ii. Liver biopsy demonstrating significantly decreased or absent alanine: glyoxylate aminotransferase (AGT) enzyme activity
 - b. Documentation of one of the following:
 - i. Elevated urine oxalate (UOx) excretion as measured by body surface area-normalized daily UOx output greater than upper limit of normal (ULN)
 - ii. Elevated UOx excretion as measured by UOx: creatinine ratio above age-specific upper limit of normal (ULN) OR
 - iii. Elevated plasma oxalate (POx) concentration (POx concentration greater than ULN)
 - c. Documentation of a trial of high fluid intake of at least three liters per meter-squared of Body Surface Area (BSA) per day and that high fluid intake will continue with therapy
 - d. Concurrent use of pyridoxine or previous trial of at least three months with no significant improvement in urine oxalate concentration
2. For patients established on therapy (within the previous year):
 - a. Documentation of a clinically significant reduction in urine or plasma oxalate levels relative to pre-treatment baseline
 - b. Patient continues with concurrent high fluid intake (at least three liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a nephrologist or urologist

COVERAGE DURATION

Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months

OTHER CRITERIA

N/A

PCSK9 INHIBITORS _ MEDICARE PART B

MEDICATION(S)

LEQVIO

COVERED USES

N/A

EXCLUSION CRITERIA

- Concomitant use with another PCSK9 inhibitor
- Non-familial hyperlipidemia/hypercholesterolemia
- Primary prevention of ASCVD

REQUIRED MEDICAL INFORMATION

For initial authorization

1.One of the following:

a.Provider attestation of a trial and failure of at least eight weeks of therapy with a high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering

OR

b.Provider attestation of statin intolerance, defined as one of the following:

i.Rhabdomyolysis

ii.Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation

iii.Elevated liver enzymes

OR

c.The patient has an FDA labeled contraindication to a statin

2.Must meet listed criteria below for each specific diagnosis:

a.For familial hypercholesterolemia (FH), one of the following must be met:

i.A “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix)

OR

ii.Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1

OR

iii.LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns

OR

- iv. Presence of xanthomas
- b. For ASCVD, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following:
 - i. Acute coronary syndromes
 - ii. History of myocardial infarction
 - iii. Stable/unstable angina
 - iv. Coronary or other arterial revascularization
 - v. Stroke or transient ischemic attack
 - vi. Peripheral artery disease presumed to be of atherosclerotic origin
 - vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin

For initial reauthorization: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA

N/A

PREVYMIS_MEDICARE PART B

MEDICATION(S)

PREVYMIS 240 MG/12 ML VIAL, PREVYMIS 480 MG/24 ML VIAL

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new start), all the following must be met:

a. Member is within 100 days post allogeneic transplant

b. Cytomegalovirus (CMV) Recipient positive

c. Member has ONE of the following:

i. Graft Versus Host Disease (GVHD) requiring greater than or equal to 1 mg/kg/day use of prednisone [or equivalent]

ii. Receipt of lymphocyte depleting therapy (such as anti-thymocyte globulin [ATG], anti-thymocyte globulin equine [ATGAM], anti-thymocyte globulin rabbit [thymoglobulin], alemtuzumab, fludarabine) within the previous six months

iii. Transplant was a cord blood allograft

iv. History of CMV drug resistance within the past six months

d. Medical rationale provided for not using oral formulation (such as patient is unable to swallow)

2. For patient established on therapy (within the previous year): Documentation of response to therapy or medical rationale for continuation beyond 100 days post-transplant

AGE RESTRICTION

May be approved for 18 years and older.

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hematologist, oncologist, or Infectious Disease specialist.

COVERAGE DURATION

Authorization will be approved for three months, up to 100 days post-transplant

OTHER CRITERIA

N/A

PROPHYLACTIC HEREDITARY ANGIOEDEMA THERAPY_MEDICARE PART B

MEDICATION(S)

CINRYZE

COVERED USES

N/A

EXCLUSION CRITERIA

Combination prophylaxis therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), all of the following criteria (a-d) must be met:

a. Documented history of one of the following clinical criteria:

i. Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria, or

ii. Recurrent, self-remitting abdominal pain without clear organic etiology, or

iii. Recurrent laryngeal edema

b. Documentation of greater than or equal to two HAE attacks per month on average for the past three months despite removal of triggers (e.g., estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary,

c. One of the following:

i. For HAE Type I and Type II, documentation of the following (per laboratory standard):

1. Serum C4 level is below the lower limit of normal, and

2. One of the following:

a. C1-inhibitor (C1-INH) protein level less than 50 percent of the lower limit of normal, or

b. C1-INH protein function less than 50 percent of the lower limit of normal

ii. For HAE with normal C1-INH or HAE Type III, one of the following:

1. Confirmed Factor 12 (FXII), ANGPT1, PLG, or KNG1 gene mutation, or
2. Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids.

d. Documentation of trial and failure or contraindication to Haegarda®.

2. For patients established on therapy (within the previous year): Documentation must be provided showing benefit of therapy with reduction of frequency and severity of HAE attack episodes by at least 50% from baseline.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an immunologist or an allergist.

COVERAGE DURATION

Initial authorization will be approved for three months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

PROVENGE_MEDICARE PART B

MEDICATION(S)

PROVENGE

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization will be approved for 3 complete doses administered at approximately 2 week intervals (6 weeks) for one course of therapy per lifetime.

OTHER CRITERIA

N/A

PULMONARY ARTERIAL HYPERTENSION _ MEDICARE PART B

MEDICATION(S)

EPOPROSTENOL SODIUM, FLOLAN, REMODULIN, REVATIO 10 MG/12.5 ML VIAL, SILDENAFIL 10 MG/12.5 ML VIAL, TREPROSTINIL, TYVASO, TYVASO INSTITUTIONAL START KIT, TYVASO REFILL KIT, TYVASO STARTER KIT, UPTRAVI 1,800 MCG VIAL, VELETRI, VENTAVIS

COVERED USES

N/A

EXCLUSION CRITERIA

Heart failure caused by reduced left ventricular ejection fraction for epoprostenol (Flolan®, Veletri®)

REQUIRED MEDICAL INFORMATION

COVERED USES:

1. Pulmonary Arterial Hypertension
2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO Group 3) for Tyvaso® only

The following criteria must be documented:

1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by:
 - a. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at restAND
 - b. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHgAND
 - c. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)AND
2. Patient has one of the following:
 - a. Documented World Health Organization (WHO) Group 1 classification (PAH) and a WHO/New York Heart Association (NYHA) functional class status as outlined below:
 - i. Flolan®, Veletri®, Tyvaso® and Ventavis®: Class III or IV
 - ii. Remodulin®, Uptravi® and Revatio® injection: Class II, III, or IV
 - b. For Tyvaso® only, WHO Group 3 classification PH-ILD

Reauthorization: Documentation of response to therapy, such as lack of disease progression or improvement in WHO functional class

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or cardiologist

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A

RADICAVA

MEDICATION(S)

RADICAVA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy, all the following criteria (a-d) must be met:
 - a. Documentation of definite or probable amyotrophic lateral sclerosis (ALS) within the previous two years per the El Escorial (Airlie House) Criteria
 - b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with at least two points in each individual item
 - c. Forced vital capacity (FVC) of at least 80% (taken within the past three months)
 - d. Dosing is in accordance with the FDA approved labeling
2. For patients established on therapy:
 - a. Documentation of a clinical benefit from therapy such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores. Edaravone may not be covered for patients experiencing rapid deterioration while on therapy due to lack of clinical benefit in this patient population.
 - b. Documentation that patient is not dependent on invasive ventilation or tracheostomy
 - c. Dosing is in accordance with the FDA approved labeling

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a neurologist with expertise in ALS.

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

REBLOZYL MEDICAL BENEFIT

MEDICATION(S)

REBLOZYL

COVERED USES

N/A

EXCLUSION CRITERIA

1. Evidence of active pregnancy
2. History of thrombosis

REQUIRED MEDICAL INFORMATION

For initial authorization for beta-thalassemia, all of the following must be met:

1. Diagnosis of beta-thalassemia, which can be confirmed by one of the following:
 - a. Hemoglobin analysis or genetic testing
 - b. Complete blood count that showed reduced Hgb level (less than 7 g/dL), mean corpuscular volume (MCV) between 50 and 70 fL, and mean corpuscular hemoglobin (MCH) between 12 and 20 pg
 - c. Peripheral blood smear results that show red blood cell (RBC) morphologic changes including microcytosis, hypochromia, anisocytosis, poikilocytosis and nucleated RBC
2. Documentation of symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
3. Documentation that patient is transfusion-dependent, defined as receiving at least 6-20 units RBC transfusions every 24 weeks

For continuation of therapy for beta-thalassemia beyond nine weeks, ongoing documentation of patient response to therapy must include maintenance of reduced transfusion levels

For initial authorization for myelodysplastic syndrome (MDS), all of the following must be met:

1. Documentation of symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
2. Diagnosis of MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
3. Documentation of ring sideroblasts greater than or equal to 15% or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation
4. Documentation of a score of very low to intermediate risk based on the Revised International Prognostic Scoring System
5. Documentation that patient requires RBC transfusions of at least two units every eight weeks
6. One of the following:

- a. Documented trial and failure [of at least two months], intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin) with or without a granulocyte-colony stimulating factor (such as filgrastim)
- b. Documentation of endogenous erythropoietin level greater than 500 mU/mL

For reauthorization for MDS: Documentation that patient was able to achieve transfusion independence for at least eight weeks during previous treatment period

AGE RESTRICTION

At least 18 years of age

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a hematologist

COVERAGE DURATION

Beta-thalassemia: Initial authorization will be for nine weeks. Reauthorization will be for one year.

MDS-RS: Initial authorization will be for six months. Reauthorization will be for one year.

OTHER CRITERIA

N/A

REBYOTA

MEDICATION(S)

REBYOTA

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Authorization for the prevention of recurrence of Clostridioides difficile infection (CDI) requires all the following criteria be met:

1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode. Episodes must have occurred less than eight weeks after completion of treatment for a previous episode.
2. Positive stool test for C. difficile within 30 days before prior authorization request
3. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist

COVERAGE DURATION

Authorization will be approved for one treatment course per primary episode. Subsequent requests must meet initial authorization criteria.

OTHER CRITERIA

N/A

RETHYMIC

MEDICATION(S)

RETHYMIC

COVERED USES

N/A

EXCLUSION CRITERIA

- Patients with severe combined immunodeficiency (SCID)
- Patients with heart surgery anticipated within four weeks prior to, or three months after, treatment
- Patients with pre-existing cytomegalovirus (CMV) infection or human immunodeficiency virus (HIV) infection
- Repeat administration of allogenic processed thymus tissue implant or previous history of thymus transplant
- Patients over 18 years of age

REQUIRED MEDICAL INFORMATION

For authorization of a one-time implant, all the following must be met:

1. Diagnosis of congenital athymia confirmed by all the following criteria:
 - a. Absence of genetic markers of severe combined immunodeficiency (SCID)
 - b. Flow cytometry, defined as one of the following:
 - i. Less than 50 naïve T cells/mm³ in the peripheral blood
 - ii. Less than 5% of total T cells being naïve in phenotype
 - c. One of the following:
 - i. Genetic defect associated with congenital athymia [such as 22q11.2 deletion syndrome, forkhead box protein N1 (FOXP1) deficiency]
 - ii. CHARGE syndrome
2. Documentation that infection control measures, including immunoprophylaxis, will be maintained until thymic function is established (immune reconstitution sufficient to protect from infection is unlikely to develop until 6-12 months after treatment)
3. Attestation from provider of absence of comorbidities, in the opinion of the treating clinician, that are reasonably likely to result in severe complications, including death, from administration of allogenic processed thymus tissue
4. Dose will not exceed 42 slices

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a pediatric immunologist.

COVERAGE DURATION

Authorization will be for one dose per lifetime. Repeat administration will not be covered.

OTHER CRITERIA

N/A

RITUXIMAB _MEDICARE PART B

MEDICATION(S)

RIABNI, RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

I. For initiation of therapy (new starts), both of the following criteria must be met:

a. For non-preferred rituximab products: Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs).

b. Requests for rituximab may be approved for the following indications when the criteria below are met:

i. For Oncologic Diagnoses: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher

ii. For Rheumatoid Arthritis:

1. Documentation of trial, failure, intolerance, or contraindication to at least one of the following targeted immune modulators: etanercept (Enbrel®), adalimumab (Humira®), or a preferred infliximab product AND

2. Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.

iii. For Vasculitis, including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):

1. Documentation that rituximab will be given in combination with glucocorticoids, AND

2. Documentation of severe disease (for example, critical organ system involvement)

iv. For Immune Thrombocytopenia (ITP):

1. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy, AND

2. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30,000 cells per microliter

v. For Relapsing and Remitting Multiple Sclerosis (RRMS): One of the following:

1. Documentation of trial, failure, or intolerance, to at least two disease modifying therapies indicated for RRMS, OR

2.Documentation that patient has highly active or aggressive disease

vi.For Refractory Myasthenia Gravis:

1.Documentation that patient has severely impaired function due to myasthenia gravis, AND

2.Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies:

a.Acetylcholinesterase inhibitors (for example, pyridostigmine)

b.Corticosteroids (for example, prednisone, methylprednisolone)

c.Immunosuppressive agents (for example, azathioprine, cyclosporine, mycophenolate)

d.Plasma exchange

vii.For Autoimmune Hemolytic Anemia (AIHA):

1.Diagnosis of warm AIHA and documentation of trial, failure, intolerance, or contraindication to glucocorticoids, OR

2.Diagnosis of cold AIHA or cold agglutinin disease

viii.Confirmed diagnosis of Neuromyelitis Optica (NMO)

ix.Confirmed diagnosis of Moderate to Severe Pemphigus Vulgaris (PV)

II.For patients established on therapy with the requested product (within the previous year): Documentation of adequate response to the medication must be provided.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a specialist for the respective indication such as: an oncologist, hematologist, rheumatologist, neurologist (in the case of RRMS, NMO), dermatologist (in the case of PV), or nephrologist (in the case of renal disease).

COVERAGE DURATION

For oncologic diagnoses: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

For non-oncologic diagnoses: Initial authorization will be approved for six months and reauthorization will be approved until no longer eligible with the plan, subject to formulary and.or benefit changes

OTHER CRITERIA

N/A

RYPLAZIM

MEDICATION(S)

RYPLAZIM

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization, all the following criteria must be met:

1. Diagnosis of plasminogen deficiency type 1 confirmed by one of the following:
 - a. Genetic testing (biallelic pathogenic variants in PLG gene), or
 - b. Confirmed hypoplasminogenemia (reduced plasminogen protein levels and functional activity)
2. Documentation of plasminogen activity level of 45% or lower of laboratory standard within the previous six months
3. Documentation of clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing)

For initial reauthorization, the following criteria must be met:

1. Documented positive response to therapy, defined as improvement in lesion number/size or improved function from baseline

For subsequent reauthorization, the following criteria must be met:

1. Documentation of no new or recurring lesions
2. Documentation that trough plasminogen activity levels are maintained at least 10% above baseline trough levels (indicating absence of anti-plasminogen antibodies)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a geneticist, hematologist, pulmonologist, ophthalmologist, and/or pediatric subspecialist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for six months.

OTHER CRITERIA

N/A

SAPHNELO

MEDICATION(S)

SAPHNELO

COVERED USES

N/A

EXCLUSION CRITERIA

Anifrolumab will not be approved if any of the following are present:

1. Severe active lupus nephritis
2. Severe active central nervous system lupus
3. Current use of other biologic immunomodulators
4. Concurrent use of voclosporin (Lupkynis®) or belimumab (Benlysta®)

REQUIRED MEDICAL INFORMATION

All of the following must be met:

Initial authorization:

1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist

AND

2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:

- a. Positive Antinuclear antibody (ANA)
- b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
- c. Positive anti-Smith (Anti-Sm)
- d. Positive anti-Ro/SSA and anti-La/SSB antibodies

AND

3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:

- a. Oral corticosteroid(s)
- b. Azathioprine
- c. Methotrexate
- d. Mycophenolate mofetil
- e. Hydroxychloroquine
- f. Chloroquine
- g. Cyclophosphamide

AND

4. Documentation that patient will continue to receive standard therapy (such as, corticosteroids,

hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

Reauthorization:

1. Documentation of positive clinical response to anifrolumab (such as, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of anifrolumab)
2. Patient currently receiving standard therapy for SLE

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA

N/A

SCENESSE MEDICAL BENEFIT

MEDICATION(S)

SCENESSE

COVERED USES

N/A

EXCLUSION CRITERIA

1. Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma
2. Personal history of melanoma or dysplastic nevus syndrome
3. Erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) with significant hepatic involvement

REQUIRED MEDICAL INFORMATION

1. For initial authorization, all the following criteria must be met:
 - a. Confirmed diagnosis of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) by one of the following:
 - i. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation
 - ii. Elevated total erythrocyte protoporphyrin greater than 80 mcg/dL AND erythrocyte fractionation shows more than 50% metal-free vs. zinc protoporphyrin
 - b. Documentation of characteristic symptoms of EPP/XLP phototoxicity (such as intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)
 - c. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/ XLP-associated painful skin reactions
 - d. Documentation that the condition is having a significant impact on quality of life (QOL)
2. For reauthorization: documentation of a positive response to therapy by of one of the following:
 - a. Decreased severity and number of phototoxic reactions
 - b. Increased duration of sun exposure
 - c. Increased quality of life
3. For request of more than three implants per year: medical justification must be provided addressing why member needs coverage for more than six months out of the year (afamelanotide is typically given during periods of high sunlight exposure, such as from spring to autumn)

AGE RESTRICTION

Approved for 18 years of age or older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with a dermatologist or porphyria specialist

COVERAGE DURATION

Initial and reauthorization will be approved for six months for three implants (Medical justification is required for requests beyond three implants for seasonal coverage)

OTHER CRITERIA

N/A

SIGNIFOR LAR_ MEDICARE PART B

MEDICATION(S)

SIGNIFOR LAR

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For patients initiating therapy (new starts), must meet criteria for indications listed below
 - a. Treatment of patients with acromegaly:
 - i. Documentation that the patient has persistent disease (e.g., biochemical or clinical) following surgical resection or patient is ineligible for surgery, AND
 - ii. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy or lanreotide subcutaneous depot injection. Note: Mild symptoms of disease are typically treated with a dopamine agonist (e.g., cabergoline)
 - b. Patients with Cushing's disease:
 - i. Confirmed diagnosis of endogenous Cushing's Disease, AND
 - ii. Documentation that patient has failed pituitary surgery or is not a candidate for surgery

2. For patients established on therapy (within the previous year), must meet indication-specific criteria below:
 - a. For Acromegaly: documentation of response to therapy, as defined as normalization of insulin-like growth factor (IGF)-1 and reduction of symptoms
 - b. For Cushing's disease: documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an endocrinologist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

SKYSONA

MEDICATION(S)

SKYSONA

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For authorization, ALL of the following must be met:

1. Patient has early active cerebral adrenoleukodystrophy (CALD) defined by ALL of the following:
 - a. Elevated very-long-chain fatty acid (VLCFA) values
 - b. Confirmed Adenosine Triphosphate (ATP)-binding cassette, subfamily D, member 1 (ABCD1) mutation
 - c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating:
 - i. Loes score between 0.5 and 9 (inclusive) on the 34-point scale
 - ii. Gadolinium enhancement on MRI of demyelinating lesions
 - d. Neurologic Function Score (NFS) of 1 or less
2. Documentation is provided indicating that patient has NONE of the following:
 - a. History of hematopoietic stem cell transplant (HSCT)
 - b. History of elivaldogene autotemcel treatment
 - c. HLA-matched willing sibling donor

AGE RESTRICTION

May be approved for patients aged 4-17 years

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a pediatric metabolic geneticist, neurologist, endocrinologist, hematologist, or oncologist

COVERAGE DURATION

Authorization is limited to one treatment course per lifetime. Approval duration will be for 12 weeks.

OTHER CRITERIA

N/A

SOLIRIS_ MEDICARE PART B

MEDICATION(S)

SOLIRIS

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent therapy with another FDA-approved product for PNH, meaning Ultomiris® or Empaveli®, unless in a four-week period of cross-titration between Soliris® and Empaveli®

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet the indication-specific criteria below:

a. For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:

i. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64), AND

ii. Severe disease as indicated by at least one of the following:

- Documented history of thrombosis, OR

- Documentation of at least 10% PNH type III red cells AND at least one of the following:

- o Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)

- o Disabling fatigue

- o End-organ complications

- o Frequent pain paroxysms (e.g., dysphagia or abdominal pain)

- o Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

iii. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)

iv. Dose and frequency is in accordance with FDA-approved labeling

b. For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:

i. Diagnosis of non-infectious HUS, meaning HUS is not due to infection with Shiga toxin-producing *Escherichia coli*

ii. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)

iii. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)

iv. Dose and frequency is in accordance with FDA-approved labeling

c. For Generalized Myasthenia Gravis (gMG), all of the following must be met:

- i. Anti-acetylcholine receptor (anti-AChR) antibody positive
 - ii. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
 - iii. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
 - iv. Failed treatment for at least one year with the following:
 - At least TWO immunosuppressive therapies (such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids), OR
 - ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIg) or plasma exchange (PE)
 - v. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
 - vi. Dose and frequency is in accordance with FDA-approved labeling
- d. For Neuromyelitis Optica Spectrum Disorder (NMOSD), all the following must be met:
- i. Diagnosis of NMOSD as defined as the following:
 - Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions), AND
 - Anti-AQP4 antibody positive
 - ii. Documentation that other alternative diagnoses have been excluded, such as multiple sclerosis
 - iii. Trial and failure, intolerance (such as neutropenia, LFT elevation, hypogammaglobulinemia) or contraindication to rituximab AND satralizumab (Enspryng®)
 - iv. Documentation that medication will not be used in combination with complement inhibitor (e.g., ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
 - v. Dose and frequency is in accordance with FDA-approved labeling
2. For patients established on the requested medication within the previous year, must meet the indication-specific criteria below:
- a. For PNH:
 - i. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
 - ii. Dose and frequency is in accordance with FDA-approved labeling
 - b. For HUS:
 - i. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
 - Maintenance of platelet counts, meaning improvements or reductions less than 25%
 - Reductions in LDH
 - Reduction in number of needed plasmaphoresis or plasma infusion events
 - Improvement in kidney function and reduction of dialysis
 - ii. Dose and frequency is in accordance with FDA-approved labeling
 - c. For gMG:
 - i. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from baseline.
 - ii. Dose and frequency is in accordance with FDA-approved labeling

d.For NMOSD:

i.Documentation of positive clinical response to therapy

ii.Documentation that medication will not be used in combination with complement inhibitor (e.g., ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)

iii.Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

PNH or HUS: Prescribed by an hematologist/oncologist or nephrologist

gMG or NMOSD: Prescribed by a neurologist

COVERAGE DURATION

Initial authorization will be approved for three months and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

SOMATOSTATIN ANALOGS _MEDICARE PART B

MEDICATION(S)

LANREOTIDE ACETATE, SANDOSTATIN LAR DEPOT, SOMATULINE DEPOT

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet the indication specific criteria below:

a. For Acromegaly:

- i. Confirmed diagnosis of acromegaly
- ii. Documentation of an inadequate response to surgery or pituitary irradiation, or patient is not a candidate for surgical resection and pituitary irradiation
- iii. Documentation of good response and tolerability to short-acting octreotide

b. For Carcinoid Tumors:

- i. Treatment is for symptomatic diarrhea or flushing:
- ii. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
- iii. Documentation of good response and tolerability to short-acting octreotide

c. For Vasoactive Intestinal Peptide Tumors

- i. Treatment is for symptomatic diarrhea
- ii. Documentation that patient has severe diarrhea caused by vasoactive intestinal peptide tumors
- iii. Documentation of good response and tolerability to short-acting octreotide

d. For Chemotherapy induced diarrhea, Sandostatin LAR® may be covered if all of the following criteria are met:

- i. Documentation that patient has severe diarrhea caused by chemotherapy
- ii. Documentation of an inadequate response or contraindication to loperamide
- iii. Documentation of good response and tolerability to short-acting octreotide

e. For AIDS-related diarrhea (Sandostatin LAR® only):

- i. Documentation that patient has severe diarrhea
- ii. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate (Lomotil®)

iii. Documentation of good response and tolerability to short-acting octreotide

f. For oncologic diagnoses: use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

2. For patients established on the requested therapy within the previous year, must meet indication specific criteria below:

a. For acromegaly: documentation of a positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

b. For carcinoid tumors: requires documentation of an improvement in the number of diarrhea and flushing episodes

c. For vasoactive intestinal peptide tumors, chemotherapy-induced diarrhea, and AIDS-related diarrhea: requires documentation of an improvement in the number of diarrhea episodes

d. For oncologic diagnoses: documentation of positive response to therapy

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

SPEVIGO

MEDICATION(S)

SPEVIGO

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria must be met:

1. Diagnosis of generalized pustular psoriasis (GPP), confirmed by both of the following:
 - a. Primary, sterile, macroscopically visible pustules on non-acral skin AND
 - b. Pustulation is not restricted to psoriatic plaques
2. Presence of an acute flare of generalized pustular psoriasis of moderate to severe intensity, as defined by:
 - a. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 3 or greater AND
 - b. The presence of new or worsening pustules AND
 - c. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or greater AND
 - d. At least 5% of body surface area (BSA) with erythema and the presence of pustules
3. Dosing must be in accordance with FDA-approved labeling

Requests for one additional dose may be approved one week after initial dose for treatment of the same flare if the following criteria are met:

1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher AND
2. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or higher
3. Dosing must be in accordance with FDA-approved labeling

For reauthorization, all of the following criteria must be met:

1. All criteria for initial authorization must be met AND
2. Documentation of a clinical response to prior treatment with spesolimab, defined as achieving a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1

AGE RESTRICTION

May be approved for patients aged 18 years and older.

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a dermatologist.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for two weeks, limited to one 900 mg (2 vials) infusion.

OTHER CRITERIA

N/A

SPINRAZA MEDICAL BENEFIT

MEDICATION(S)

SPINRAZA

COVERED USES

N/A

EXCLUSION CRITERIA

1. Concomitant use with, or following, gene therapy for SMA (such as onasemnogene abeparvovec)
2. Use in combination with risdiplam (Evrysdi®)
3. Advanced symptoms of SMA (such as complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION

For initial authorization, all the following criteria must be met:

1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to three copies of SMN2, AND
2. Documentation that patient is presymptomatic or has symptoms with an onset at age less than 30 years, AND
3. Documentation of baseline motor function, with one of the following standardized test appropriate based on the patient's age and level of function:
 - a. CHOP-INTEND: Children's hospital of Philadelphia Infant Test of Neuromuscular Disorders
 - b. HINE: Hammersmith Infant Neurological Examination
 - c. HFSME: Hammersmith Functional Motor Scale Expanded
 - d. 6MWT: six-minute walk test
 - e. RULM: Revised Upper Limb Module

NOTE the following guidance on selecting an appropriate test:

- Non-sitters (infants and kids): CHOP-INTEND, HINE (may need HFSME as they transition to sitting).
- Sitters: HFSME, RULM
- Walkers (kids): 6MWT, HFSME
- Walkers (adults): 6MWT, RULM
- Non-walkers (adults): RULM

For reauthorization: Improvement or maintenance of motor function, evidenced by stabilization or improvement in motor function test scores performed at baseline.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

SPRAVATO

MEDICATION(S)

SPRAVATO

COVERED USES

N/A

EXCLUSION CRITERIA

- Concomitant use with another dissociative agent
- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
- History of intracerebral hemorrhage
- Current or prior DSM-5 diagnosis of a psychotic disorder or MDD with psychosis, bipolar or related disorders, comorbid obsessive compulsive disorder, intellectual disability, autism spectrum disorder, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder
- Current or recent history (i.e. within the last six months) of moderate or severe substance or alcohol use disorder

REQUIRED MEDICAL INFORMATION

For initiation of therapy, all the following criteria (1-4) must be met:

1. Confirmed diagnosis of one of the following:

a. For treatment-resistant depression (TRD), clinical documentation must be provided that outlines the patient evaluation. TRD is defined as use of the following regimens (i and ii) for the current depressive episode:

i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD).

ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly).

b. For MDD with acute suicidal ideation or behavior, documentation must be provided that patient has current suicidal ideation with intent defined as both of the following:

i. Patient has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide, and

ii. Patient intends to act on thoughts of killing themselves.

2. Baseline score from one of the following standardized depression rating scales confirming severe depression:

a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20

- b. Hamilton Depression Scale (HAMD17) score of at least 24
 - c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16
 - d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28
3. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling
- For patients established on therapy, all the following criteria must be met:
- 1. Documentation of clinical improvement or sustained improvement from baseline in depression symptoms, documented by depression rating scores
 - 2. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
 - 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling

AGE RESTRICTION

Approved for 18 years and older

PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a psychiatrist or a psychiatric nurse practitioner.

COVERAGE DURATION

Initial authorization will be approved for three months. Reauthorization will be approved for six months.

OTHER CRITERIA

N/A

SYFOVRE

MEDICATION(S)

SYFOVRE

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

- History of or active choroidal neovascularization (CNV), associated with AMD or any other cause
- History of ocular or periocular infections
- History of endophthalmitis, retinal detachments, or increased intraocular pressure

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria must be met:

1. Documentation of diagnosis of geographic atrophy (GA) confirmed by clinical exam or diagnostic imaging (such as Color Fundus Photography, Fundus Autofluorescence, Near Infrared Reflectance Imaging, Optical Coherence Tomography)
2. Documentation that GA is secondary to age-related macular degeneration (AMD)

For reauthorization, the following must be met: Documentation of response to therapy defined as one of the following:

1. Reduction in GA growth lesion
2. Documentation of improvement in visual function through visual function assessment test (such as normal luminance best-correct visual acuity [BCVA], maximum reading speed, Functional Reading Independence Index, microperimetry)

AGE RESTRICTION

May be approved for patients age equal to 60 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year

OTHER CRITERIA

N/A

SYLVANT_MEDICAL BENEFIT

MEDICATION(S)

SYLVANT

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Initial Authorization:

1. Confirmed diagnosis of Multicentric Castleman Disease (MCD)

AND

2. Documentation of negative human immunodeficiency virus (HIV) status

AND

3. Documentation of negative human herpes-virus 8 (HHV-8) status

AND

4. Documentation that siltuximab (Sylvant®) will be used as a single agent

Reauthorization will require positive response to therapy as well as documentation that patient remains HIV and HHV-8 negative.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an oncologist, hematologist, or rheumatologist.

COVERAGE DURATION

Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

T-CELL THERAPY

MEDICATION(S)

ABECMA, BREYANZI, CARVYKTI, KYMRIAH, TECARTUS, TECVAYLI, YESCARTA

COVERED USES

N/A

EXCLUSION CRITERIA

Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy. Repeat administration of T-cell therapy is considered experimental and investigational because the effectiveness of this approach has not been established.

REQUIRED MEDICAL INFORMATION

For all chimeric antigen receptor therapy (CAR-T) therapy requests, the following criteria must be met:

1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher
2. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver)
3. One of the following regarding functional status must be met:
 - a. For Kymriah® for B-cell precursor acute lymphoblastic leukemia (ALL) only: Karnofsky or Lansky Scale greater than or equal to 50%
 - b. Provider attestation/documentation that the patient's functional status is sufficient to undergo treatment. This may include but is not limited to a documented Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 or a written statement acknowledging that the patient is fit to tolerate therapy.
4. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)
5. For B-cell lymphomas, patient does not have primary central nervous system lymphoma

For Tecvayli®:

1. Confirmed diagnosis of multiple myeloma
2. Refractory or relapsed disease to four or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
3. Asymptomatic or minimally symptomatic with Eastern Cooperative Oncology Group (ECOG) performance status 0-1
4. No evidence of active systemic infection

AGE RESTRICTION

Abecma®: Approved for 18 years of age and older

Breyanzi®: Approved for 18 years of age and older

Carvykti®: Approved for 18 years of age and older

Kymriah®:

- Approved for 25 years of age or younger for acute lymphoblastic leukemia (ALL)
- Approved for 18 years of age and older for relapsed or refractory B-cell lymphomas

Tecartus®: Approved for 18 years of age and older

Yescarta®: Approved for 18 years of age and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an oncologist

COVERAGE DURATION

For Tecvayli®: Initial authorization and reauthorization will be approved for one year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose.

For all other immunotherapies: Two months (limited to one treatment course per lifetime, with four doses of tocilizumab [Actemra®] at up to 800 mg per dose).

OTHER CRITERIA

N/A

TEPEZZA MEDICAL BENEFIT

MEDICATION(S)

TEPEZZA

COVERED USES

N/A

EXCLUSION CRITERIA

Sight-threatening thyroid eye disease (defined as presence of direct optic neuropathy or corneal breakdown)

REQUIRED MEDICAL INFORMATION

All of the following criteria must be met:

1. Confirmed diagnosis of moderate-to-severe thyroid eye disease/Grave's Orbitopathy, as defined as eye disease that significantly impacts quality of life and at least one of the following:
 - a. Lid retraction of at least 2 mm, marginal reflex distance-1 (MRD1) greater than four, or presence of lagophthalmos
 - b. Moderate or severe soft-tissue involvement (such as swelling or redness of the eyes)
 - c. Inconstant diplopia (diplopia at extremes of gaze) or constant diplopia (continuous diplopia in primary or reading position)
2. Documentation of active disease, defined as a Clinical Activity Score (CAS) of at least four
3. Laboratory evidence of euthyroid state
4. Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) unless there is a contraindication, intolerance, or presence of proptosis or diplopia.
5. Dosing is within the Food and Drug Administration approved label dose

Reauthorization is not considered medically necessary and will not be covered.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an ophthalmologist.

COVERAGE DURATION

Authorization will be approved for six months for a total of up to eight infusions

OTHER CRITERIA

N/A

TESTOSTERONE REPLACEMENT THERAPY(TRT)_MEDICARE PART B

MEDICATION(S)

AVEED, TESTOPEL, TESTOSTERONE 100 MG PELLETT, TESTOSTERONE 200 MG PELLETT, TESTOSTERONE 50 MG PELLETT

COVERED USES

N/A

EXCLUSION CRITERIA

- Use for improvement of sexual signs and symptoms (such as decreased libido, sexual dysfunction)
- Use in patients with breast cancer or untreated prostate cancer

REQUIRED MEDICAL INFORMATION

Medicare Part B – criteria based on Local Coverage Determination - L36569

- 1.For initiation of testosterone replacement therapy (new starts), must meet all the following criteria
 - a.One of the following confirmed diagnoses:
 - i.Diagnosis of gender dysphoria or gender identity disorder OR
 - ii.Diagnosis of clinical hypogonadism, defined as meeting the following (1-3):
 - 1.At least two separate serum testosterone levels taken on two different days in the morning (when testosterone secretion is highest), and / or two morning levels of “free” or bioavailable testosterone) indicating low testosterone levels
 - 2.Elevated luteinizing hormone (LH) or follicle-stimulating hormone (FSH) levels.
 - 3.Presence of low testosterone associated symptoms (such as decreased energy, sleep disturbances, anemia, hot flushes, etc)
 - b.Documented trial and failure (defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms) of both of the following:
 - i.Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump), and
 - ii.Generic injectable testosterone cypionate.
- 2.For patients established on the requested testosterone replacement therapy (within the previous year): Documentation of positive response to therapy and ongoing monitoring of hormone levels
- 3.For estrogen replacement therapy: The use of a subcutaneous pellet formations of estrogen is considered investigational for all indications.

QUANTITY LIMIT:

Testopel® is limited to a maximum of six pellets per insertion

Medicare may only cover the number of pellets actually implanted in the patient (maximum of six pellets), wastage is not covered. Use of additional pellets may be paid on appeal if the documentation supports medical necessity as determined by the FDA approved drug label and the service complies with all Medicare requirements as indicated above.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

TEZSPIRE MEDICARE PART B

MEDICATION(S)

TEZSPIRE 210 MG/1.91 ML SYRING

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication

REQUIRED MEDICAL INFORMATION

1. For patients initiating therapy, all the following criteria must be met:

a. Documentation of treatment with high-dose inhaled corticosteroid (ICS) plus an inhaled long-acting beta-2 agonist (LABA) and has been adherent to therapy in the past three months (this may be verified by pharmacy claims information),

b. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following

i. Asthma Control Questionnaire (ACQ) score greater than equal to 1.5,

ii. At least two asthma exacerbations require oral corticosteroids for at least three days in last 12 months,

iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit

c. For patients with eosinophilic asthma or steroid-dependent asthma: Documented trial and failure, intolerance, or contraindication to therapy with dupilumab (Dupixent®)

AGE RESTRICTION

May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

OTHER CRITERIA

N/A

THROMBOCYTOPENIA MEDICATIONS _ MEDICARE PART B

MEDICATION(S)

NPLATE

COVERED USES

N/A

EXCLUSION CRITERIA

Concomitant use with other thrombopoietin receptor agonists (e.g., Mupleta®, Promacta®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

REQUIRED MEDICAL INFORMATION

For initiation of therapy, must meet indication-specific criteria below:

1. For Immune Thrombocytopenia (ITP), Nplate®, may be covered if all the following criteria (a-c) are met:

a. Diagnosis of chronic immune thrombocytopenia (ITP)

b. Platelet count of less than 30,000 cells per microliter

c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated:

i. Systemic corticosteroids

ii. Immune globulin

iii. Splenectomy

iv. Rituximab

2. For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], Nplate® may be covered if all the following criteria (a-b) are met:

a. Documentation of acute exposure to radiation, and

b. Documentation of myelosuppression defined as leukopenia, thrombocytopenia, or anemia

For patients established on therapy, must meet indication-specific criteria below:

1. For ITP:

a. Documentation of improved platelet levels from baseline

b. Documentation the continued therapy is medically necessary to maintain a platelet count of at least 50,000 cells per microliter

2. For HSARS: Members must meet the initial approval criteria above for each request

QUANTITY LIMIT:

Nplate®: Weekly dose below 10 microgram/kg

•Quantity should be rounded down to the nearest available vial size within 10% of calculated dose and is

subject to audit. Nplate is available in 125-, 250-, and 500- mcg single-dose vials of lyophilized powder.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an oncologist, hematologist, gastroenterologist or hepatologist.

COVERAGE DURATION

For ITP: Initial authorization will be approved for six months. Reauthorization will be approved for one year

For HSARS: Authorization will be approved for three months

OTHER CRITERIA

N/A

TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)

AMVUTTRA, ONPATTRO

COVERED USES

N/A

EXCLUSION CRITERIA

- New York Heart Association (NYHA) Heart Functional class III or IV
- History of liver transplantation
- Peripheral neuropathy attributed to causes other than hATTR
- Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as Amvuttra® (vutrisiran), inotersen (Tegsedi®), patisiran (Onpattro®), or tafamidis (Vyndaqel®, Vyndamax®)]

REQUIRED MEDICAL INFORMATION

For initial authorization, all of the following criteria must be met:

1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
AND
2. Documentation of a pathogenic TTR mutation
AND
3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II
AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
AND
5. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of the following:
 - a. Peripheral sensorimotor polyneuropathy (such as tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
 - b. Autonomic neuropathy symptoms (such as orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])
6. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization:

1. Documentation that patient is tolerating applicable therapy (vutrisiran (Amvuttra®), inotersen (Tegsedi®))

or patisiran (Onpattro®))

AND

2. Documented improvement or stabilization in polyneuropathy symptoms from baseline, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures:

- a. Baseline polyneuropathy disability (PND) score
- b. Familial amyloid polyneuropathy (FAP) stage

AGE RESTRICTION

Approved for patients 18 years of age and older

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA

N/A

TYSABRI_MEDICARE PART B

MEDICATION(S)

TYSABRI

COVERED USES

N/A

EXCLUSION CRITERIA

1. Use of natalizumab in combination with other disease modifying therapy (DMT) to treat patients with multiple sclerosis (e.g., dimethyl fumarate, glatiramer).
2. Use of natalizumab in combination with immunosuppressants or TNF inhibitors (e.g., adalimumab) .

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet indication-specific criteria below:
 - a. For Multiple Sclerosis:
 - i. One of the following:
 1. Documentation of trial, failure, or intolerance to at least one of the following disease modifying therapies:
 - a. Interferon therapy (Avonex®, Rebif®, Plegridy®, or Betaseron®)
 - b. Generic dimethyl fumarate
 - c. glatiramer acetate (Copaxone®)
 - d. teriflunomide (Aubagio®)
 - e. fingolimod (Gilenya®)
 - f. ocrelizumab (Ocrevus®)
 - g. ozanimod hydrochloride (Zeposia®)
 - h. siponimod (Mayzent®)

OR

2. Documentation that patient has highly active or aggressive disease defined as one of the following:
 - a. Relapse leading to deterioration in physical functioning or disabilities
 - b. Magnetic resonance imaging (MRI) findings of new or worsening lesions
 - c. Manifestations of multiple sclerosis-related cognitive impairment

AND

- ii. Negative anti-JCV antibody status. If patient is anti-JCV antibody positive, the patient must meet the following criteria:
 1. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil, AND
 2. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

b. For Crohn's disease:

i. Diagnosis of moderate to severe Crohn's disease, AND

ii. Documentation of trial, failure, intolerance, or lack of response to a formulary TNF inhibitor (Remicade® and/or Humira®) indicated for Crohn's, AND

iii. Negative anti-JCV antibody status. If patient is anti-JCV antibody positive, the patient must meet the following criteria:

1. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, and mycophenolate mofeti, AND

2. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

2. For patients established on therapy (within the previous year): Documentation of response to therapy must be provided

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by either a neurologist (for multiple sclerosis) or gastroenterologist (for Crohn's disease)

COVERAGE DURATION

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

TZIELD

MEDICATION(S)

TZIELD

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

Stage 3 (symptomatic) type 1 diabetes

REQUIRED MEDICAL INFORMATION

Initial authorization requires all the following be met:

1. Diagnosis of stage 2 type 1 diabetes (meaning that the patient is at risk of developing symptomatic type 1 diabetes) as evidenced by both the following (a and b):

a. Documentation of the presence of two or more of the following autoantibodies:

- Glutamic acid decarboxylase 65 (GAD) autoantibody
- Insulin autoantibody (IAA)
- Insulinoma-associated antigen 2 autoantibody (IA-2A)
- Zinc transporter 8 autoantibody (ZnT8A)
- Islet cell autoantibody (ICA)

b. Evidence of dysglycemia without overt hyperglycemia confirmed by an oral glucose tolerance test (meaning a 2-hour post prandial blood glucose of 140-199 mg/dL)

Note: If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be considered such as fasting plasma glucose 100–125 mg/dL

2. Dosing is within FDA-labeled guidelines

AGE RESTRICTION

May be approved for patients aged eight years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, an endocrinologist

COVERAGE DURATION

Authorization will be approved for one 14-day treatment course per lifetime

OTHER CRITERIA

N/A

ULTOMIRIS_MEDICARE PART B

MEDICATION(S)

ULTOMIRIS

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent therapy with Soliris® or Empaveli®

REQUIRED MEDICAL INFORMATION

For Paroxysmal Nocturnal Hemoglobinuria (PNH):

1. For initiation of therapy (new starts) all the following criteria (a-c) must be met:

a. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycoposphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64), and

b. Severe disease as indicated by at least one of the following (i or ii):

i. Documented history of thrombosis, OR

ii. Documentation of at least 10% PNH type III red cells AND at least one of the following:

iii. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)

iv. Disabling fatigue

v. End-organ complications

vi. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)

vii. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

c. Dose and frequency is in accordance with FDA-approved labeling

2. For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:

a. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1a above) and severe disease (criteria 1b above). However, this can be based on patient's history prior to starting eculizumab.

b. Dose and frequency are in accordance with FDA-approved labeling

3. For patients established on the requested agent for PNH, both of the following criteria must be met for continuation of therapy:

a. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms, and

b. Dose and frequency are in accordance with FDA-approved labeling

For Complement-Mediated Hemolytic Uremic Syndrome (HUS)

1. For initiation of therapy (new starts) all the following criteria (a-c) must be met:
 - a. Diagnosis of non-infectious HUS, meaning HUS is not due to infection with Shiga toxin-producing *Escherichia coli*, and
 - b. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
 - c. Dose and frequency are in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for HUS, both of the following criteria must be met
 - a. Confirmed documentation of Complement-Mediated Hemolytic Uremic Syndrome (criteria 1a and 1b above). However, this can be based on patient's history prior to starting eculizumab, and
 - b. Dose and frequency are in accordance with FDA-approved labeling
3. For patients established on the requested agent for HUS, both of the following criteria must be met:
 - a. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
 - i. Maintenance of platelet counts, defined as an improvement or reduction less than 25%
 - ii. Reductions in LDH
 - iii. Reduction in number of needed plasmapheresis or plasma infusion events
 - iv. Improvement in kidney function and reduction of dialysis
 - b. Dose and frequency are in accordance with FDA-approved labeling

For Generalized Myasthenia Gravis (gMG), all the following must be met:

1. Anti-acetylcholine receptor (anti-AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
3. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
4. Failed treatment for at least one year with ONE of the following:
 - A. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids)
 - B. ONE immunosuppressive therapy and required at least four infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)
5. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization for Myasthenia Gravis (MG):

1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from baseline.
2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

The patient's age must be within FDA labeling for the requested indication

PRESCRIBER RESTRICTION

- PNH or HUS: Prescribed by a hematologist/oncologist or nephrologist
- MG or NMOSD: Prescribed by a neurologist

COVERAGE DURATION

Initial authorization for up to three months and reauthorization will be approved for up to one year.

OTHER CRITERIA

N/A

UPLIZNA_MEDICARE PART B

MEDICATION(S)

UPLIZNA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts) for Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
 - a. Diagnosis of neuromyelitis optica spectrum disorder as defined as both of the following:
 - i. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions), AND
 - ii. Anti-AQP4 antibody positive
 - b. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)
 - c. Trial and failure, intolerance, or contraindication to rituximab
 - d. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
 - e. Dose and frequency is in accordance with FDA-approved labeling
2. For patients established on therapy (within the previous year) for Neuromyelitis Optica Spectrum Disorder (NMOSD):
 - a. Documentation of positive clinical response to therapy
 - b. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
 - c. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a neurologist or ophthalmologist

COVERAGE DURATION

Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

VYEPTI_MEDICARE PART B

MEDICATION(S)

VYEPTI

COVERED USES

N/A

EXCLUSION CRITERIA

Concomitant use with another calcitonin gene-related (CGRP) agent

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy for migraine prophylaxis (chronic and episodic):
 - a. Diagnosis of migraine headaches with at least four (4) headache days per month AND
 - b. One of the following:
 - i. Trial and inadequate response to at least six weeks of at least one (1) prophylactic medication from one (1) of the following categories:
 1. Anticonvulsants (i.e., divalproex, valproate, topiramate)
 2. Beta-blockers (i.e., metoprolol, propranolol, timolol)
 3. Antidepressants (i.e., amitriptyline, venlafaxine)
 - ii. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above, AND
 - c. The patient has been evaluated for, and does not have, medication overuse headache
 - d. Documented trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig®, Emgality®, Ajovy®, or Qulipta®)
 - e. For patients established on botulinum toxin for migraine prophylaxis, combination therapy may be considered medically necessary if the following criteria are met:
 - i. The patient has been established on, and adherent to botulinum toxin for at least six months and has a documented 30% reduction in headache days from baseline
 - ii. Patient continues to have at least four headache days per month with headaches lasting four hours or longer, despite use of botulinum toxin prophylaxis monotherapy
 - iii. Combination therapy is prescribed by, or in consultation with, a neurologist
2. For patients established on therapy within the previous year: Documented reduction in the severity or frequency of headaches.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Initial authorization will be approved for six months.

Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

VYVGART_MEDICARE PART B

MEDICATION(S)

VYVGART

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For initiation of therapy (new starts) for Generalized Myasthenia Gravis (gMG), all the following must be met (1-5):

1. Anti-acetylcholine receptor (anti-AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
3. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of five or greater
4. History of failure of at least two immunosuppressive agents over the course of at least 12 months (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids) or has an intolerance or contraindication to these therapies
5. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy (within the previous year) for Generalized Myasthenia Gravis (gMG), all the following must be met (1-2):

1. Documentation of improvement in MG-ADL by at least two points from baseline
2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION

May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a neurologist or rheumatologist

COVERAGE DURATION

Initial authorization will be approved for six months. Reauthorization will be approved for one year.

OTHER CRITERIA

N/A

XIAFLEX MEDICAL BENEFIT

MEDICATION(S)

XIAFLEX

COVERED USES

N/A

EXCLUSION CRITERIA

EXCLUSION CRITERIA:

- PD involving the urethra.
- More than three total injections per affected cord for DC
- More than eight total injections per lifetime for PD.

REQUIRED MEDICAL INFORMATION

Initial Authorization Criteria:

For Dupuytren's contracture (DC):

1. Both of the following diagnostic criteria:
 - a. Finger flexion contracture of at least 20° with a palpable cord in a metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint
 - b. Documentation of a positive "table top test," defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top
2. Documentation that affected joint has not had surgical intervention within the previous 90 days

For Peyronie's disease (PD):

1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound
3. Patient has intact erectile function, with or without the use of medications
4. Documentation of a functional impairment that is expected to improve with treatment (e.g., inability to have intercourse despite intact erectile function, due to curvature)
5. Documentation showing the patient does not have any of the following:
 - a. Significant pain with palpation of the plaque
 - b. Lack of full erectile response to prostaglandin E1 during curvature measurement
 - c. Ventral curvature
 - d. Calcified plaque
 - e. Plaque located proximal to the base of the penis
6. Documentation that the patient has been counseled on expectations of treatment (e.g., expected average

curvature reduction is 17 degrees without reduction in pain or erectile dysfunction, potential for adverse effects)

Reauthorization Criteria:

For DC:

1. Documentation of fewer than three total injections in affected cord.

For PD

1. Documentation that the curvature of the penis remains greater than 15 degrees. Limited to eight total injections per lifetime.

AGE RESTRICTION

Approved for 18 years and older

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For DC:

Initial authorization will be approved for three months for a maximum of three treatment courses.

Reauthorization will be approved for three months, not to exceed three injections per affected cord.

For PD:

Initial authorization will be approved for three months, not to exceed four injections. Reauthorization will be approved for six months, not to exceed eight injections per lifetime.

OTHER CRITERIA

N/A

XOLAIR_ MEDICARE PART B

MEDICATION(S)

XOLAIR

COVERED USES

N/A

EXCLUSION CRITERIA

Concurrent use with another therapeutic immunomodulator agent utilized for the same indication

REQUIRED MEDICAL INFORMATION

1. For initiation of therapy (new starts), must meet indication-specific criteria below:
 - a. For asthma, must meet all of the following criteria:
 - i. Diagnosis of moderate to severe persistent allergic asthma
 - ii. IgE baseline levels greater than 30 IU/ml
 - iii. Positive skin test to a common perennial aeroallergens
 - iv. Documentation that in the past three months patient is adherent to a combination of a medium/high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)
 - v. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
 1. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
 2. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months
 3. At least one exacerbation requiring hospitalization
 - b. For chronic idiopathic urticaria, must meet all of the following criteria:
 - i. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out, AND
 - ii. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine), AND
 - iii. Trial and failure of one additional medication from the following classes:
 1. leukotriene receptor antagonists (e.g., montelukast),
 2. first generation H1 antihistamine (e.g., diphenhydramine), or
 3. histamine H2-receptor antagonist (e.g., famotidine, ranitidine)
 - c. For nasal polyps, must meet all the following criteria:
 - i. Evidence of bilateral nasal polyposis by direct examination, endoscopy or sinus CT scan
 - ii. Documentation of one of the following:
 1. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
 2. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral

systemic corticosteroids

iii. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids

iv. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids, nasal saline irrigation) in combination with omalizumab

2. For patients established on the requested therapy within the previous year, must meet indication-specific criteria below:

a. For asthma: documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

b. For chronic idiopathic urticarial: documentation of response to therapy (e.g. reduction in flares or oral steroid dose).

c. For nasal polyps: documentation of positive clinical response to therapy such as symptom improvement

AGE RESTRICTION

Treatment of asthma: Approved for six years of age or older.

Treatment of urticaria: Approved for 12 years of age or older.

Treatment of nasal polyps: Approved for 18 years of age or older.

PRESCRIBER RESTRICTION

Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist

Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)

Nasal polyps: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist or immunologist

COVERAGE DURATION

Urticaria and nasal polyps: Initial authorization will be for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA

N/A

ZINPLAVA MEDICAL BENEFIT

MEDICATION(S)

ZINPLAVA

COVERED USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

All the following criteria must be met for Clostridioides difficile infection (CDI):

1. Previous trial of standard-of-care antibiotic regimen for recurrent CDI (such as oral vancomycin, fidaxomicin)
2. Bezlotoxumab (Zinplava®) must be used in combination with standard-of-care antibiotics for treatment (such as oral vancomycin, fidaxomicin)
3. Dosing is within Food and Drug Administration's approved labeling
4. For Commercial/Medicare Part B only: Patient has at least one risk factor for higher likelihood of recurrent CDI [for example, age of 65 years or older, history of CDI in the previous six months, compromised immunity, clinically severe CDI (defined as a Zar score greater than or equal to 2, scores range from 1 to 8, with higher scores indicating more severe infection)]

Reauthorization requires all the following criteria to be met:

1. Previous dose was at least 12 months prior
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline
3. Bezlotoxumab (Zinplava®) is used in combination with standard-of-care antibiotics for treatment (such as oral vancomycin, fidaxomicin)
4. Dosing is within Food and Drug Administration's approved labeling

AGE RESTRICTION

Approved for 18 years of age and older

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist

COVERAGE DURATION

Initial authorization and reauthorization will be approved for a one-time intravenous

OTHER CRITERIA

N/A

ZOLGENSMA _MEDICAL BENEFIT

MEDICATION(S)

ZOLGENSMA

COVERED USES

N/A

EXCLUSION CRITERIA

- Use in combination with nusinersen (Spinraza®) or risdiplam (Evrysdi®) therapy
- Repeat infusion of onasemnogene abeparvovec
- Advanced symptoms of SMA (such as, complete paralysis of limbs, tracheostomy or ongoing invasive ventilator support in the absence of an acute reversible illness)

REQUIRED MEDICAL INFORMATION

1. Confirmed genetic diagnosis of spinal muscular atrophy (SMA) with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to three copies of SMN2
2. Documentation that premedication with prednisolone 1 mg/kg/day (or equivalent) will be started 24 hours prior to infusion and continue for at least 30 days
3. Documentation of baseline anti-AAV9 antibody titers of less than or equal to 1:50
4. Documentation of baseline tests for liver function, platelet count, and troponin-I

AGE RESTRICTION

May be covered for patients two years of age and under

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a neurologist

COVERAGE DURATION

Authorization will be approved for a one-time infusion

OTHER CRITERIA

N/A

ZYNTEGLO

MEDICATION(S)

ZYNTEGLO

COVERED USES

All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For beta-thalassemia, Zynteglo® may be approved when all the following criteria are met:

1. Documented diagnosis of beta-thalassemia confirmed by genetic testing
2. Patient has transfusion-dependent disease defined as one of the following:
 - a. History of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs)
 - b. Eight or more transfusions of pRBCs per year in the two years preceding therapy
3. Patient is clinically stable and eligible to undergo the pre-conditioning regimen and infusion regimen
4. Patient does not have any of the following:
 - a. Prior history of receiving a hematopoietic stem-cell transplant
 - b. Prior history of receiving gene therapy for the requested indication
 - c. Advanced liver disease (such as evidence of cirrhosis and/or persistent alanine aminotransferase, aspartate transferase or direct bilirubin values greater than three times the upper limit of normal)
 - d. Evidence of severe iron overload (such as T2* less than 10 ms by magnetic resonance imaging (MRI) or other evidence of severe iron overload in the opinion of treating physician)

AGE RESTRICTION

May be approved for patients aged four years and older

PRESCRIBER RESTRICTION

Must be prescribed by, or in consultation with, a hematologist

COVERAGE DURATION

Authorization will be limited to one treatment course per lifetime

OTHER CRITERIA

N/A