Providence
Medicare Advantage Plans

PROVIDENCE MEDICARE ADVANTAGE PLANS

2023 PRIOR AUTHORIZATION CRITERIA FOR PART B DRUGS

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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.

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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.

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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

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 Erythematous (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
For SLE without active lupus nephritis:
Age five years and older for IV infusion
Age 18 years and older for subcutaneous injection

For SLE with Active Lupus Nephritis:
Age 18 years and older for IV infusion or subcutaneous injection

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a rheumatologist or nephrologist

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, 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

BRINEURA - MEDICAL BENEFIT

MEDICATION(S)
BRINEURA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization all the following criteria must be met:
1. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) confirmed by both of the following:
a. Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity (in a sample of leukocytes, fibroblasts, dried blood spot or saliva)
b. Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2 gene
2. Documentation of symptomatic disease (e.g., seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures)
3. Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least
one (1)

Reauthorization requires documentation of response to therapy, defined as both of the following:
1. No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale
2. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

AGE RESTRICTION
May be covered for ages 3-17 years

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

COVERAGE DURATION
Initial approval and reauthorization will be for 1 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

CAR-T - MEDICAL BENEFIT

MEDICATION(S)

ABECMA, BREYANZI, KYMRIAH, TECARTUS, YESCARTA

COVERED USES

N/A

EXCLUSION CRITERIA

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

REQUIRED MEDICAL INFORMATION

For all indications, the following criteria must be met:

1. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver)

For B-cell precursor acute lymphoblastic leukemia (ALL), Kymriah®, TecartusTM may be approved when all the following criteria are met:

1. Documentation of cluster of differentiation 19 (CD19) positive, B-cell precursor acute lymphoblastic leukemia (ALL), and
2. Documentation of relapsed or refractory disease, as defined by one of the following scenarios:

a. For Kymriah®:

i. Second or later bone marrow relapse, or

ii. Bone marrow relapse after allogenic stem cell transplant, or

iii. Primary refractory (not achieving a complete response after two cycles of standard chemotherapy), or

iv. Chemorefractory (not achieving a complete response after one cycle of standard chemotherapy for relapsed disease)

b. For Tecartus™:

i. First relapse if first remission is less than or equal to 12 months, or

ii. Bone marrow relapse after allogeneic stem cell transplant, or

iii. Primary refractory disease, or

iv. Chemo-refractory after two or more lines of systemic therapy

3. For Philadelphia chromosome (Ph)-positive disease only: Have failed adequate trials of, contraindication, or intolerance to two prior lines of tyrosine kinase inhibitor (TKI) therapy (for example, imatinib, dasatinib, nilotinib, ponatinib)
4. Performance score:

a. Kymriah®: Karnofsky or Lansky Scale greater than or equal to 50%

b. Tecartus™: Eastern Cooperative Oncology Group (ECOG) performance status 0-1

5. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For relapsed or refractory B-cell lymphoma, Breyanzi®, Yescarta® or Kymriah® may be approved when all the following criteria are met:
1. Confirmed diagnosis of relapsed or refractory FDA approved B-cell lymphomas
2. Refractory or relapsed disease to two or more prior treatment regimens. Prior therapy must have included the following unless otherwise not indicated/tolerated:
a. An anthracycline containing chemotherapy regimen (such as doxorubicin), and
b. Anti-CD20 monoclonal antibody (such as rituximab)
3. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
4. Member does not have any of the following:
a. Primary central nervous system (CNS) lymphoma
b. Evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For relapsed or refractory mantle cell lymphoma (MCL), Tecartus™ may be approved when all the following criteria are met:
1. Histologically confirmed mantle-cell lymphoma [cyclin D1 overexpression or chromosomal translocation)]
2. Disease is considered relapsed or refractory
3. Previous use to the following therapy: anthracycline or bendamustine containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy
4. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
5. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For multiple myeloma, Abecma®, Carvykti® may be approved when all the following criteria are met:
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 large B-cell lymphoma
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
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

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 treatment of insulin-dependent diabetes when all of 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 treated a rapid-acting insulin (such as Humalog®) or regular insulin (such as Humulin R®). This may be verified by pharmacy claim for rapid-acting or regular insulin within the previous 120 days

Replacement of Continuous Glucose Monitors
II. 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.
III. 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/Freestyle Libre/Libre 2: 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:
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), 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

DIABETIC DURABLE MEDICAL EQUIPMENT (DME)

MEDICATION(S)
DEXCOM G4 TRANSMITTER, DEXCOM G5 TRANSMITTER, DEXCOM G6 TRANSMITTER

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-preferred test strips and/or blood glucose meter:
1. Patient is using an insulin pump that requires a meter that synchronizes with their pump.
OR
2. Patient has physical or mental limitations that makes utilizing BOTH of the preferred products (manufactured by Roche and LifeScan) unsafe, inaccurate, or otherwise not feasible

Test strip quantity exceptions:
1. For patients using a continuous glucose monitoring systems for personal use: Patients that have been approved for use of a continuous glucose monitor for personal use will be restricted to the following:
Dexcom G6 or Freestyle Libre: 50 test strips per 90-day supply.
Dexcom G5: 450 test strips per 90-day supply

• An additional 50 test strips per 90-day supply may be approved with documentation that the patient has low blood glucose levels requiring verification with test strips at least two times per week. Requests above this are not considered medically necessary. Coverage may be allowed with discontinuation of continuous glucose monitoring system and is subject to strip quantity criteria below

2. For patients using traditional “finger-stick” glucose monitors, quantities up to 10 strips per day may be covered if the patient meets one of the following criteria:
a. Patient has a diagnosis of Type 1 diabetes mellitus (T1DM)
b. Patient is currently using an insulin pump
c. Patient has an intensive insulin regimen (more than three insulin injections per day)
d. Patient is pregnant
e. Patient is less than 18 years of age
f. Prescriber provides clinical rationale to support the need for additional testing
3. For patients using traditional “finger-stick” glucose monitors, quantities exceeding 10 strips per day are not considered medically necessary and will not be covered

For reauthorization of quantity exceptions, all of the following are required:
1. Documentation that the patient continues to need the requested quantity
2. Documentation that there is a clinical benefit associated with the increased quantity.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization will be approved for 12 months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

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):
For initial authorization, all of the following must be met:
1. 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 glycophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
2. Severe disease as defined by at least one of the following (a or b):
a. Documented history of thrombosis, OR
b. Documentation of at least 10% PNH type III red cells AND at least one of the following:
i. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

Reauthorization:
1. Documentation of reduced LDH levels, reduced transfusion requirements, 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

ENZYME REPLACEMENT THERAPY - MEDICAL BENEFIT

MEDICATION(S)
ALDURAZYME, CEREZYME, ELAPRASE, ELELYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, VIMIZIM, VPRIV

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization both of the following must be met:
1. Documentation of FDA-labeled indication for the requested product
AND
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®)

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.

REAUTHORIZATION:
Both of the following must be met:
1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).
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.

AGE RESTRICTION
- Aldurazyme®: N/A
- Cerezyme®: The safety and efficacy have not been established in patients less than two years of age
- Elaprase®: The safety and efficacy have not been established in patients less than 16 months of age
- Elelyso®: The safety and efficacy have not been established in patients less than four years of age

• Fabrazyme®: The safety and efficacy not established in patients under two years of age
• Kanuma®: N/A
• Lumizyme®: N/A
• Mepsevii®: N/A
• Naglazyme®: N/A
• Nexviazyme®: The safety and efficacy have not been established in patients less than one year of age
• Vimizim®: The safety and effectiveness have not been established in patients less than five years of age
• Vpriv®: The safety and efficacy have not been established in patients less than four years of age

PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with a Hepatologist, Endocrinologist, Medical Geneticist, Cardiologist, Pulmonologist, or Bone and Mineral specialist.

COVERAGE DURATION

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

OTHER CRITERIA

N/A

ERYTHROPOIESIS STIMULATING AGENTS (ESAS) - MEDICARE PART B

MEDICATION(S)

ARANESP, EPOGEN, PROCRIT, RETACRIT

COVERED USES

N/A

EXCLUSION CRITERIA

•Patients with uncontrolled hypertension
•Anemia induced from hepatitis C therapy
•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-10D50.0, 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
•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.

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 to100 mcg/L or serum transferrin saturation more than or equal to20%
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) AND
ii.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%
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 (e.g., 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

Reauthorization:
1. Documentation of continued medical necessity (e.g., 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)

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 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

GAMIFANT - MEDICAL BENEFIT

MEDICATION(S)
GAMIFANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initiation Criteria:
1. One of the following (a, b, or c):
a. Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on genetic mutation known to cause HLH (e.g., PRF1, UNC13D, STX11 and STXBP2)
b. Family history consistent with primary HLH
c. Five out of the following eight criteria fulfilled:
i. Fever
ii. Splenomegaly
iii. Cytopenias affecting two of three lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100,000 cells per microliter, neutrophils less than 1,000 cells per microliter
iv. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
vi. Low or absent NK-cell activity
vii. Ferritin equal or greater than 500 mcg/L
viii. Soluble CD25 equal or greater than 2400 U/mL
2. Documentation that patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin)
3. Documentation that patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will be discontinued at the initiation of conditioning for stem cell transplant
4. Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling
5. Documentation that patient currently has no active infection (e.g., mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:

1. Patient continues to be a candidate for stem cell transplant
2. Documentation of positive clinical response such as improvement in the following clinical and laboratory parameters: fever, splenomegaly, central nervous system symptoms, complete blood count, fibrinogen and/or D-dimer, ferritin, and soluble CD25 (also referred to as soluble interleukin-2 receptor) levels
3. Documentation that patient is being monitored for serious infections (such as tuberculosis, adenovirus, EBV, and CMV)
4. Documentation that dose does not exceed max FDA approved dosing of 10 mg/kg per dose for two doses per week

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with a hematologist or oncologist

COVERAGE DURATION
Initial authorization approved for three months, reauthorization for one month.

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, LUPANETA PACK, 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

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)
EVKEEZA

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

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 Hyperesosinophilic 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 rational should be provided and exceptions will be considered on a case by cases 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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an appropriate specialist (such as a Neurologist for multiple sclerosis or an immunologist, hematologist or infections disease expert for primary immunodeficiency).

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 1 MG VIAL, BORTEZOMIB 2.5 MG VIAL, BORTEZOMIB 3.5 MG IV VIAL, BORTEZOMIB 3.5 MG VIAL, COSELA, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, ELZONRIS, EMPLICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, FYARRO, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JELMYTO, JEMPERLI, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KIMMTRAK, KYPROLIS, LIBTAYO, LUMOXITI, LUTATHERA, MARGENZA, MELPHALAN HCL, MONJUVI, MVASI, NELARABINE, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO, OPDUALAG, PACLITAXEL PROTEIN-BOUND, PADCEV, PEPAXTO, PERJETA, PHESGO, PLUVICTO, POLIVY, PORTRAZZA, POTELIGEO, ROMIDEPSIN, RYBREVANT, RYLAZE, SARCLISA, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TIVDAK, TORISEL, TRAZIMERA, TREANDA, TRODELVY, VECTIBIX, VELCADE, VIDAZA, 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_ILARIS_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 12 weeks.

OTHER CRITERIA
N/A

MEDICAL NUTRITION - MEDICARE PART B

MEDICATION(S)
RELIZORB

COVERED USES
All Medically-Accepted Indications

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 evidence 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

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 - ORPHAN DRUGS

MEDICATION(S)
NULIBRY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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 (e.g., high-quality peer reviewed literature, guidelines, other clinical information)

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 (e.g., 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 Nulibry®: Initial authorization will be approved for three months. Reauthorization will be approved for 12

months.
For all other indications: Initial authorization will be approved for one year and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
N/A

MIRCERA - MEDICAL BENEFIT

MEDICATION(S)
MIRCERA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the treatment of adults with anemia associated with chronic kidney disease:
1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy
2. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%

For the treatment of pediatric patients five 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:
1. Documented hemodialysis for at least eight weeks
2. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
3. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

Reauthorization:
1. Documentation of continued medical necessity (such as ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12g/dl or HCT levels of less than or equal to 36% within previous 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for one year.

OTHER CRITERIA

N/A

OPHTHALMIC VEGF INHIBITORS_MEDICARE PART B

MEDICATION(S)
BEOVU, 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

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

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

PNEUMOCOCCAL VACCINES - MEDICARE PART B

MEDICATION(S)
PREVNAR 20, VAXNEUVANCE

COVERED USES
N/A

EXCLUSION CRITERIA
• PCV13 will not be covered for patients over 19 years of age
• PCV15 and PCV20 will not be covered for patients less than 19 years of age

REQUIRED MEDICAL INFORMATION
1. One dose of PCV15 (Vaxneuvance®) or PCV20 (Prevnar 20®) will be covered for patients aged 19 years and older
2. One dose of PPSV23 (Pneumovax®) will be covered for patients with previous immunization history (may be verified by pharmacy or medical claims) for PCV13 (Prevnar 13®) or PCV15
a. A second dose of PPSV23 may be covered if patients are considered immunocompromised.

QUANITY LIMITS:
PCV15, PCV20: one dose per lifetime

AGE RESTRICTION
PPSV23: Authorization required for patients over the age of three years

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved for three months for one injection

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

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

EXCLUSION CRITERIA

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

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 rest

AND

b. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg

AND

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 - MEDICAL BENEFIT

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
4. Documented baseline Hgb level of at least 9 g/dL, drawn within the previous 30 days

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) and 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

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 (FOXN1) 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 allogeneic 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
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 (e.g., corticosteroids,

hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

Reauthorization:
1. Documentation of positive clinical response to anifrolumab (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 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
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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

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:
1.Documented history of thrombosis, OR
2.Documentation of at least 10% PNH type III red cells AND at least one of the following:
a.Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
b.Disabling fatigue
c.End-organ complications
d.Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
e.Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
iii.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.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:
1.At least TWO immunosuppressive therapies (such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids), OR
2.ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIg) or plasma exchange (PE)
v.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:
1.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
2.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 either satralizumab (Enspryng®) or inebilizumab (Uplizna®)
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:
1.Maintenance of platelet counts, meaning improvements or reductions less than 25%
2.Reductions in LDH
3.Reduction in number of needed plasmaphoresis or plasma infusion events
4.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

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): 6WWT, 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 last 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

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

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 1 year.

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 two 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 of at least three
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) in combination with mycophenolate
a. For patients who have intolerance or contraindication to mycophenolate: Trial and failure of at least two weeks of monotherapy with high-dose intravenous (IV) glucocorticoid therapy will be required unless the patient is unable to use intravenous (IV) glucocorticoids due to a contraindication (such as evidence of viral hepatitis, significant hepatic dysfunction, severe cardiovascular morbidity, or psychiatric disorders)

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 eight infusions

OTHER CRITERIA

N/A

TESTOSTERONE REPLACEMENT THERAPY (TRT) - MEDICARE PART B

MEDICATION(S)
AVEED, TESTOPEL, TESTOSTERONE 100 MG PELLET, TESTOSTERONE 200 MG PELLET, TESTOSTERONE 50 MG PELLET

COVERED USES
N/A

EXCLUSION CRITERIA
Use for improvement of sexual signs and symptoms (e.g., decreased libido, sexual dysfunction)

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy (new starts), must meet all of the following criteria
a. One of the following confirmed diagnoses:
i. Diagnosis of gender dysphoria or gender identity disorder OR
ii. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism
Documented trial and failure (defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms) of both generic topical testosterone 1% and generic injectable testosterone cypionate.

2. For patients established on the requested therapy (within the previous year): Documentation of positive response to therapy

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

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., Mulpleta®, 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

TOTAL PARENTERAL NUTRITION (TPN)- MEDICARE PART B

MEDICATION(S)

AMINOSYN, AMINOSYN II, AMINOSYN II WITH ELECTROLYTES, AMINOSYN M, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E, CLINISOL, CLINOLIPID, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, TRAVASOL, TROPHAMINE

COVERED USES

N/A

EXCLUSION CRITERIA

Parenteral nutritional therapies are not covered under Medicare Part B in situations involving temporary impairments. Non-Part B uses may be coverable under the Part D benefit.

REQUIRED MEDICAL INFORMATION

1. Documentation that the member has a medical condition which does not allow for absorption of sufficient nutrients to maintain weight and strength as defined by one of the following:

a. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients, or

b. A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system

AND

2. Documentation that the condition is of long and indefinite duration as deemed by the judgment of the attending provider or substantiated in the medical records

AND

3. Documentation that enteral nutrition has been considered and ruled out, tried and been found ineffective, or that enteral nutrition exacerbates gastrointestinal tract dysfunction

AND

4. The treating provider has evaluated the member within 30 days prior to initiation of parenteral nutrition. If the treating provider does not see the beneficiary within this timeframe, they must document the reason

why and describe what other monitoring methods were used to evaluate the beneficiary's parenteral nutrition needs.

Reauthorization requires documentation of ongoing medical necessity of total parenteral nutrition.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be approved for a minimum three months, up to 12 months.

OTHER CRITERIA
N/A

TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
ONPATTRO

COVERED USES
N/A

EXCLUSION CRITERIA
• New York Heart Association (NYHA) Heart Functional class III or IV
• Patients with type I or type II diabetes
• Uncontrolled cardiac arrhythmia or unstable angina
• History of liver transplantation
• Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as 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:
• Peripheral sensorimotor polyneuropathy (e.g., 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)
• Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])

Reauthorization:
1. Documentation that patient is tolerating applicable therapy (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

TROGARZO - MEDICARE PART B

MEDICATION(S)
TROGARZO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:

1. Inadequate response to six months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last eight weeks

a. Defined as persistent viremic failure

b. Failure must not be due to non-adherence (adherence may be verified by pharmacy claims)

2. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance to at least one antiretroviral medication from each of the three following classes:

a. Non-nucleoside reverse transcriptase inhibitor

b. Nucleoside reverse transcriptase inhibitor

c. Protease inhibitor

3. Documentation of baseline viral load

4. Confirmation that patient will take an optimized background regimen of anti-retroviral therapy (ART) along with the requested therapy

Re-authorization or continuation of therapy:

1. Patient has previously received treatment with the requested therapy

2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy)

3. Confirmation that patient will continue to take an optimized background regimen of anti-retroviral therapy (ART) with the requested therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an infectious disease specialist.

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

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

ULTOMIRIS - MEDICAL BENEFIT

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 glycophosphatidylinositol (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

AGE RESTRICTION
N/A

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

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

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 is in accordance with FDA-approved labeling

AGE RESTRICTION
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by a neurologist

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
N/A

REQUIRED MEDICAL INFORMATION
For Dupuytren's contracture:
1. Both of the following diagnostic criteria:
a. Finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a 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:
1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a stable curvature of the penis that is between 30 and 90 degrees with a palpable plaque 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. Isolated hourglass deformity
d. Ventral curvature
e. Calcified plaque
f. 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 after the initial two treatment cycles (four injections) will require documentation that the

curvature of the penis remains greater than 15 degrees

AGE RESTRICTION

Approved for 18 years and olde

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

For Dupuytren’s contracture: Authorization will be approved for three months for a maximum of two treatment courses.

For Peyronie’s disease: 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
Patients with existing heart failure

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met for Clostridioides difficile infection (CDI):
1. Previous trial of standard-of-care antibiotic regimen for recurrent CDI (e.g., oral vancomycin, fidaxomicin)
AND
2. Patient has at least one risk factor for higher likelihood of recurrent CDI (e.g. an age of 65 years or older, a history of C. difficile infection in the previous six months, compromised immunity, clinically severe C. difficile infection (defined as a Zar score greater than or equal to 2, scores range from 1 to 8, with higher scores indicating more severe infection))
AND
3. Bezlotoxumab (Zinplava®) must be used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin)

Reauthorization requires:
1. Previous dose was at least 12 months prior
AND
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline
AND
3. Bezlotoxumab (Zinplava®) is used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin)

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 dose at 10 mg/kg

(subject to audit).

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