PROVIDENCE
Medicare Advantage Plans

A division of Providence Health Assurance

PROVIDENCE MEDICARE ADVANTAGE PLANS

2022 PRIOR AUTHORIZATION CRITERIA FOR PART B DRUGS

This list pertains to the following Providence Medicare Advantage Plans:

BRIDGE 1 + Rx (HMO-POS), BRIDGE 2 + Rx (HMO-POS), CHOICE + Rx 001 (HMO-POS), CHOICE + Rx 002 (HMO-POS), COMPASS + Rx (HMO-POS), COTTONWOOD + Rx (HMO-POS), DUAL PLUS (HMO D-SNP), ENRICH + Rx (HMO), EXTRA PART B ONLY + Rx (HMO), EXTRA + Rx 001 (HMO), EXTRA + Rx 002 (HMO), FOCUS MEDICAL (HMO), HARBOR + Rx (HMO), LATITUDE +Rx (HMO-POS), PINE + Rx (HMO), PRIME + Rx (HMO), SELECT MEDICAL (HMO-POS), SUMMIT + Rx (HMO-POS), TIMBER + Rx (HMO), ALIGN GROUP PLANS + RX (HMO), DISCOVER GROUP PLAN + RX (HMO-POS), EXPLORE GROUP PLAN + RX (HMO-POS)

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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 (TTY users should call 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 of the following must be met:
a. Diagnosis of Hereditary Angioedema Types (HAE) I, II or III and one of the following clinical criteria:
i. Self-limiting, non-inflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
ii. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six (6) hours, or
iii. Recurrent laryngeal edema,

b. One of the following:
i. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one (1) month apart with the patient in their basal condition and after the first year of life that show:
1. C4 is less than 50 percent of the lower limit of normal, AND
2. One of the following:
a. C1-Inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
b. C1-INH function is 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, KNG1 gene mutation, OR
2. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids
c. 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.

3. For quantities exceeding the quantity limit: Documentation of frequent HAE attacks defined as greater

than or equal to two (2) attacks per month on average.

QUANTITY LIMIT (subject to audit):
Berinert® - 2 injections per 30 days
Ruconest® - 2 injections per 30 days
Kalbitor® - 2 boxes (6 vials) per 30 days

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 (6) months. Reauthorization will be approved for up to one (1) 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
I. 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 (2) 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 (6) months
ii. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) 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)

II. 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 no previous use of dialysis in the past 12 months or currently using dialysis
4. Concurrent use of Lupkynis®

REQUIRED MEDICAL INFORMATION

For Systemic Lupus Erythematous (SLE) and active lupus nephritis:

All of 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)

Reauthorization:
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)
Patient currently receiving standard therapy for SLE and active lupus nephritis

QUANTITY LIMIT:
• Belimumab 200 mg/mL single-dose prefilled auto injector and glass syringe for subcutaneous injection: 4 mL per 28 days
o Adults with SLE without active lupus nephritis allowed loading dose: none
o Adults with SLE with active lupus nephritis allowed loading dose: 400-mg dose (two 200-mg injections) once weekly for four doses, then 200 mg once weekly thereafter
• Belimumab powder for solution for IV use only (subject to audit): Initial dose of 10 mg/kg IV every two weeks for three doses and then continue every four weeks thereafter as maintenance
o Applicable to adults with SLE or active lupus nephritis and pediatric patients with SLE
• Belimumab IV is available as:
o 120 mg in a 5-mL single-dose vial
o 400 mg in a 20-mL single-dose vial for injection
• Correct vial combination for each patient should be calculated to minimize waste

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
All Food and Drug Administration (FDA) approved and selected medically accepted indications not otherwise excluded from the benefit, as outlined below.

The criteria outlined below is adapted from the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) criteria – LCD35172

Each botulinum toxin product is pharmacologically and clinically distinct, and therefore, not interchangeable with any other botulinum toxin product. As a result, approved indications for the two toxins differ… it is the responsibility of providers to use each drug in accordance with the FDA approved indications unless there are valid and documented reasons stating why the unapproved/off label form is used. “Providers should consult the package insert of each neurotoxin to identify the FDA approved indications for each product.”

1. Documentation that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions.
• An exception to this general rule is that for certain treatments including focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer’s cramp, laryngeal spasm, or dysphonia, Botulinum toxin can be an initial mode of therapy, and in these circumstances it is not necessary to show that other methods of treatment have been tried and proven unsuccessful.
2. For certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis), coverage will be limited to those conditions listed in the Covered ICD-10-CM section of the LCD.
3. Botulinum toxin can be used to reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and walking, to allow better range of motion, to permit better physical therapy, and to reduce severe spasm in order to provide adequate perineal and palmar hygiene.
4. Botulinum toxin has indications for overactive bladder and severe primary axillary hyperhidrosis,
5. Due to the rarity of severe organic writer's cramp, Medicare would not expect to see the treatment of this condition billed frequently.
6. There may be patients who require Electromyography (EMG) in order to determine the proper injection

site(s). The electromyography procedure codes specified in the HCPCS section of this policy may be covered if the physician has difficulty in determining the proper injection site(s). It should be noted that needle electromyographic procedures include the interpretation of electrical waveforms measured by equipment that produces both visible and audible components of electrical signals recorded from the muscle(s) studied by the needle electrode. Electromyography equipment must be capable of showing both visual and auditory components of the electrical activity produced by and recorded from within muscle tissue by the needle electrode for myopathy or neuropathy diagnosis. For purposes of botulinum injection guidance, the EMG tools that have audible output alone are sufficient.

7. For the appropriate initial and total doses of Botulinum toxins please consult the FDA, manufacturers' recommendations or the AHFS.

8. Coverage of treatments provided may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of a Botulinum toxin, fail to produce a satisfactory clinical response. In such situations it may be appropriate to use an alternative Botulinum toxin once in order to determine if a more satisfactory response can be obtained. Providers must also document the results of and response to these injections.

9. Requests may be considered for redetermination (formerly appeal) for continued treatment during a treatment period or for resumption at a later date if satisfactory results have not been obtained and compelling clinical evidence of medical necessity for continued treatment is presented.

10. Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as a single limb, single eyelid, side of the face, side of the neck, both vocal cords, etc.

11. For treatment of achalasia and cardiospasm, Botulinum toxin should be used only after one or more of these conditions have been met and documented:

• The patient has failed conventional therapy.
• The patient is at high risk of complications from pneumatic dilation or surgical myotomy.
• The patient who refuses surgical myotomy or balloon dilation, in reference to a less invasive risky procedure.
• A prior myotomy or dilatation has failed
• A prior dilatation caused an esophageal perforation.
• The patient has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilatation induced perforation.

12. Botulinum Toxin is covered for prophylaxis of headaches in adult patients with chronic migraine (?15 days per month with headache lasting 4 hours a day or longer).

13. It is also covered for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

14. Treatment of skin wrinkles ICD-10 CM code L11.8,L57.2, L57.4, L66.4, L87.1, L90.3, L90.4, L92.2, L94.8, L98.5, L98.6 using Botulinum toxin is cosmetic and is not covered by Medicare.

15. Acceptance of Botulinum Toxin has not been established for the following conditions (USP DI 2006):

• Deviations over 50 prism diopters

• Restrictive strabismus
• Chronic paralytic strabismus except to reduce antagonist contracture in conjunction with surgical repair
• Duane’s syndrome with lateral rectus muscle weakness
• Recurrent temporomandibular joint (TMJ) disorder

16. Anal spasm, irritable colon, biliary dyskinesia, or any treatment of spastic conditions not listed as covered in this policy are considered to be cosmetic, investigational, or not safe and effective.

17. The use of Botulinum toxin to treat muscle tension is considered not proven effective.

18. Due to the short life of Botulinum toxin, Medicare will reimburse the unused portion of these drugs only when vials are not split between patients. Use modifier JW to code for drug wastage on a separate line of the claim form. The documentation must show in the patient's medical record the exact dosage of the drug given, exact amount and reason for unavoidable wastage, and the exact amount of the discarded portion of the drug.

19. Scheduling of more than one patient is encouraged to prevent wastage of Botulinum toxins. If a vial is split between two patients, the billing in these instances must be for the exact amount of Botulinum toxin used on each individual patient. Medicare would not expect to see billing for the full fee amount for Botulinum toxin on each beneficiary when the vial is split between two or more patients.

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

BUPRENORPHINE - PROBUPHINE/SUBLOCADE - MEDICARE PART B

MEDICATION(S)
PROBUPHINE, SUBLOCADE

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of chronic pain

REQUIRED MEDICAL INFORMATION
For Probuphine®:
Initial Authorization:
1. Documentation of opioid use disorder
2. Patient has been clinically stable for at least 3 months on 8 mg per day or less of a transmucosal buprenorphine product (i.e. Subutex® or Suboxone® sublingual tablet or generic equivalent). (The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine®)
3. Medical rational of why patient cannot be continued on maintenance therapy with a transmucosal buprenorphine product.
4. Documentation that Probuphine® will be used along with counseling and/or psychosocial support

Reauthorization:

1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that Probuphine® will be continue to be used along with counseling and/or psychosocial support
3. Documentation that this is the second course of therapy to be inserted into the contralateral arm. (Treatment beyond 2 courses has not been studied in clinical trials and is not considered medically necessary).

For Sublocade®:
Initial authorization:
1. Documentation of opioid use disorder
2. Patient is currently maintained or will be maintained on an 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection
3. Medical rationale of why therapy with a transmucosal buprenorphine product is not appropriate for this

patient
4. Documentation that Sublocade® will be used along with counseling and/or psychosocial support

Reauthorization:

1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that patient continues to receive Sublocade® along with counseling and/or psychosocial support

QUANTITY LIMIT:

For Probuphine®: 1 kit (4 implants) per 6 months, lifetime limit of 1 insertion in each arm (2 kits)
For Sublocade®: 1 injection per 28 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Probuphine®: Initial authorization and reauthorization will be approved for 6 months. Coverage will be limited to two courses of treatment (one insertion into each arm). Treatment for longer than 12-months (2 treatment courses) has not been studied in clinical trials and is not considered medically necessary.
For Sublocade®: Initial authorization and reauthorization will be approved for 6 months.

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 1 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 - MEDICARE PART B

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 (e.g., kidney) to minimize risks of serious adverse reactions (e.g., cytokine release syndrome)

For B-cell precursor acute lymphoblastic leukemia (ALL), Kymriah® may be approved when all of the following criteria are met:
1. Documentation of cluster of differentiation 19 (CD19) positive, B-cell precursor acute lymphoblastic leukemia (ALL), and
2. Disease is considered refractory, or in second or later relapse, as defined by any one of the following scenarios:
a. Second or later bone marrow relapse, or
b. Bone marrow relapse after allogenic stem cell transplant, or
c. Primary refractory (not achieving a complete response after two cycles of standard chemotherapy), or
d. Chemorefractory (not achieving a complete response after one cycle of standard chemotherapy for relapsed disease), and
3. Member is not eligible for allogenic stem cell transplant, and
4. 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 (e.g., imatinib, dasatinib, nilotinib, ponatinib)
5. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance score is 0-3
6. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)

For relapsed or refractory large B-cell lymphoma, Breyanzi®, Yescarta® or Kymriah® may be approved

when all of the following criteria are met:
1. Confirmed diagnosis of relapsed or refractory FDA approved large B-cell lymphomas
2. Refractory or relapse 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 (e.g. doxorubicin), and b. Anti-CD20 monoclonal antibody (e.g. 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), TecartusTM may be approved when all of the following criteria are met:
1. Histologically confirmed mantle-cell lymphoma [i.e. 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® may be approved when all of 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 infection (including hepatitis B or C, active graft vs. host disease)

AGE RESTRICTION
Abecma®:
1. Approved for 18 years of age and older
Breyanzi®:
2. Approved for 18 years of age and older
Kymriah®:
1. Approved for 25 years of age or younger for acute lymphoblastic leukemia (ALL)
2. Approved for 18 years of age and older for relapsed or refractory large B-cell lymphoma

TecartusTM:
1. Approved for 18 years of age and older
Yescarta®:
1. 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 800mg per dose).

OTHER CRITERIA
N/A

CGRP AGENTS FOR MIGRAINE PROPHYLAXIS_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® and Emgality®)
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

CRYSVITA - MEDICAL BENEFIT

MEDICATION(S)
CRYSVITA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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, otherwise, see appendix for ranges), and
3. One of the following:
a. Patient’s epiphyseal plate has NOT fused, or
b. Patient meets all of the following:
i. Patient’s epiphyseal plate has fused, and
ii. Patient is experiencing clinical signs and symptoms of disease (e.g., limited mobility, musculoskeletal pain, bone fractures), and
4. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced, and
5. Documentation of patient’s current weight and that dosing is in accordance with the United States Food and Drug Administration approved labeling

For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:
1. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
2. Documentation of at least one of the following responses to therapy:
a. Improvement in skeletal deformities

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

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for six (6) months and reauthorization will be approved for one (1) year.

OTHER CRITERIA
N/A

DURYSTA_MEDICARE PART B

MEDICATION(S)
DURYSTA

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

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist

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

OTHER CRITERIA
N/A

ENZYME REPLACEMENT THERAPY - MEDICAL BENEFIT

MEDICATION(S)
ALDURAZYME, CEREZYME, ELAPRASE, ELELYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, 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.

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 (i.e., 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 (i.e., high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case by case basis.

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

AGE RESTRICTION
- Aldurazyme®: N/A
- Cerezyme®: N/A

• 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®: Safety and efficacy not established in patients under two years of age
• Kanuma®: N/A
• Lumizyme®: N/A
• Mepsevii®: N/A
• Naglazyme®: N/A
• 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

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

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.

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

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 10g/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 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
b. Treatment of anemia 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 3 months) serum ferritin level ? 100 mcg/L or serum transferrin saturation ? 20%
c. Anemia associated with zidovudine-treated HIV-infection patients
i. Documented current (within last 3 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 2 units of blood)
v. Patient is unwilling or unable to donate autologous blood pre-operatively

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 (1) year. For use during chemotherapy, therapy should be discontinued 8 weeks following the final dose of myelosuppressive chemotherapy (subject to audit).

OTHER CRITERIA

N/A

EVENITY - MEDICAL BENEFIT

MEDICATION(S)
EVENITY, EVENITY (2 SYRINGES)

COVERED USES
N/A

EXCLUSION CRITERIA
Myocardial infarction or stroke within the preceding year, hypocalcemia

REQUIRED MEDICAL INFORMATION
For the treatment or prevention of osteoporosis, must meet ONE of the following criteria:
1. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
2. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one of the following:
a. Age more than 80 years
b. Chronic glucocorticoid use
c. Documented increased fall risk
3. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following:
a. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
b. Documented contraindication or intolerance to therapy with all of the following: 1. denosumab, 2. oral bisphosphonate (e.g., alendronate), and 3. IV bisphosphonate therapy (i.e., zoledronic acid)
4. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
a. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%
b. One of the following:
i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
ii. Documented contraindication or intolerance to therapy with all of the following:
1. Denosumab
2. Oral bisphosphonate (e.g., alendronate)
3. IV bisphosphonate therapy (i.e., zoledronic acid)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an endocrinologist or rheumatologist.

COVERAGE DURATION

May be approved for up to one (1) year, ensuring the total duration of Evenity® therapy does not exceed one (1) year of total therapy duration.

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.

GAMIFANT - MEDICAL BENEFIT

MEDICATION(S)
GAMIFANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initiation Criteria:
1. Diagnosis of primary HLH based on a molecular diagnosis OR family history consistent with primary HLH OR 5 out of the following 8 criteria fulfilled:
a. Fever
b. Splenomegaly
c. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100 x 109/L, neutrophils less than 1 x 109/L
d. 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)
e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
f. Low or absent NK-cell activity
g. Ferritin equal or greater than 500 mcg/L
h. Soluble CD 25 equal or greater than 2400 U/mL
2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
a. Having not responded or not achieved a satisfactory response
b. Having not maintained a satisfactory response to conventional HLH therapy
c. Intolerance to conventional HLH treatments
3. 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 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 disease improvement such as:
a. Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils more than 1x109/L, platelets more than 100x109/L, ferritin less than 2,000 µg/L, fibrinogen more than 1.50g/L, D-dimer less than 500 µg/L, normal CNS symptoms, no worsening of sCD25 more than 2-fold baseline)
b. Partial response defined as normalization of more than or equal to 3 HLH abnormalities
c. HLH improvement defined as more than or equal 3 HLH abnormalities improved by at least 50% from baseline
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 weekInitiation Criteria:
1. Diagnosis of primary HLH based on a molecular diagnosis OR family history consistent with primary HLH OR 5 out of the following 8 criteria fulfilled:
a. Fever
b. Splenomegaly
c. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100 x 109/L, neutrophils less than 1 x 109/L
d. 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)
e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
f. Low or absent NK-cell activity
g. Ferritin equal or greater than 500 mcg/L
h. Soluble CD 25 equal or greater than 2400 U/mL
2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
a. Having not responded or not achieved a satisfactory response
b. Having not maintained a satisfactory response to conventional HLH therapy
c. Intolerance to conventional HLH treatments
3. 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 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 disease improvement such as:
a. Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils more than 1x109/L, platelets more than 100x109/L, ferritin less than 2,000 µg/L, fibrinogen more than 1.50g/L, D-dimer less than 500 µg/L, normal CNS symptoms, no worsening of sCD25 more than 2-fold baseline)
b. Partial response defined as normalization of more than or equal to 3 HLH abnormalities
c. HLH improvement defined as more than or equal 3 HLH abnormalities improved by at least 50% from baseline
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 3 months, reauthorization for 1 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

MEDICATION(S)

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

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

For anemia associated with uterine leiomyomata (fibroids)
1. Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone
AND
2. Documentation that Lupron® will be used in combination with iron supplementation

For uterine leiomyomata (fibroids)
1. Documentation that surgical removal of fibroids is planned within four months
AND
2. And one of the following, less invasive surgical methods will be employed:
a. Documentation of an enlarged uterus that will require a midline rather than transverse incision.
b. Documentation that shrinking the uterus or fibroids will allow for a vaginal hysterectomy rather than an abdominal procedure.

For endometriosis:
1. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel syndrome, interstitial cystitis, urinary tract disorders)
2. For Synarel®: documented trial and failure to Lupron® with add-back progesterone therapy (such as norethindrone acetate) or Lupaneta® Pack.

Reauthorization
For Lupron® requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g. norethindrone) to help prevent bone mineral density loss.

Reauthorization
For Synarel® and Zoladex® is not recommended. Treatment is only recommended for up to six months with these agents for endometriosis

For central precocious puberty
Note, a one-time dose may be approved for diagnostic purposes
For Initial Authorization:
1. 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
2. Confirmation of diagnosis by one of the following:
a. 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)]
b. Pubertal level of basal LH levels (0.3 IU/L or greater)
c. Bone age advanced one year beyond the chronological age
AND
3. For Synarel®: documented trial and failure or contraindication/intolerance to Lupron® and, either Triptodur® or Supprelin LA®

For Reauthorization:
1. Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level), and
2. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression.

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.

For gender-affirming services:
1. Prescribed by or in consultation with an endocrinologist
2. Demonstration that puberty has progressed to a minimum of Tanner Stage 2
3. For Medicaid: request is for Vantas® (histrelin acetate 50 mg implant)

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

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® and Lupaneta® Pack – authorization/reauthorization will be approved for up to six months (total of 12 months). For Synarel®/Zoladex® - initial authorization for up to six months and no reauthorization
CPP: Authorization/reauthorization will be approved for up to one year
GID: 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
In vitro fertilization: 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 (1) 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 (4) weeks, followed by any of the three (3) maintenance dosing regimens below:
• 1.5 mg/kg once weekly
• 3 mg/kg every 2 weeks
• 6 mg/kg every 4 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 (6) months
Reauthorization: 12 months

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)

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 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.

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

OTHER CRITERIA

N/A

IMMUNE GAMMA GLOBULIN (IGG)

MEDICATION(S)

ASCENIV, BIVIGAM 5 GM/50 ML (10%) VIAL, BIVIGAM LIQUID 10% VIAL, 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 (i.e., common variable immunodeficiency), Hyper-IgM (i.e., 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 (e.g., 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 (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with 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 (i.e. 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 (i.e. prednisone or methylprednisolone)
b. Documentation of pure motor CIDP

Autoimmune Hemolytic Anemia:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. 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 (e.g. 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 (e.g., 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 (e.g., pyridostigmine)
b. Corticosteroids (e.g., prednisone, methylprednisolone)
c. Immunosuppressive agents (e.g., 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 (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an appropriate specialist (e.g., 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, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENDEKA, BESPONSA, BLENREP, BLINCYTO, BORTEZOMIB, COSELA, CYRAMZA, DACOGEN, DANYELZA, DARZALEX, DARZALEX FASPRO, DECITABINE, EMPLICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JELMYTO, JEMPERLI, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LIBTAYO, LUMOXITI, LUTATHERA, MARGENZA, MELPHALAN HCL, MONJUVI, MVASI, OGIVRI, ONIVYDE, ONTRUZANT, OPDIVO 100 MG/10 ML VIAL, OPDIVO 240 MG/24 ML VIAL, OPDIVO 40 MG/4 ML VIAL, PADCEV, PEPAXTO, PERJETA, PHESGO, POLIVY, PORTRAZZA, POTELIGEO, ROMIDEPSIN, RYBREVANT, SARCLISA, SYNRIBO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, 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.

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

KRYSTEXXA - MEDICAL BENEFIT

MEDICATION(S)
KRYSTEXXA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial therapy, all of the following criteria must be met:
1) Diagnosis of chronic gout
2) Documentation of inadequate response to both of the following medications, unless contraindication to both of the following: xanthine oxidase inhibitor (e.g., allopurinol) and uricosuric (e.g., probenecid). 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 MS

2. For treatment beyond two years or beyond two treatment courses.

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy (new starts), all of 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 (e.g. 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 6 months, AND
c. Documentation of active disease after an adequate trial at least one additional of the following disease modifying therapies, unless all are contraindicated. An adequate trial is defined as at least 6 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®)

2. For patients established on therapy (within the previous year): Documentation that patient is responding well to therapy and has not completed two years of therapy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

May be approved for up to 2 years, ensuring the cumulative duration of therapy does not exceed 2 years in a lifetime

OTHER CRITERIA

N/A

LUXTURNA - MEDICAL BENEFIT

MEDICATION(S)
LUXTURNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
All of 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, ORENCIA 250 MG VIAL, REMICADE, RENFLEXIS, SIMPONI ARIA, 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 (i.e., 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 (starting on samples will not be considered as established on therapy) within the previous year:
i. 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. For moderate to severe Ulcerative Colitis:
1. Infliximab (Remicade®) or vedolizumab (Entyvio®) may be covered
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®) or vedolizumab (Entyvio®)

ii. For moderate to severe Crohn's Disease:
1. Infliximab (Remicade®) may be covered
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®)

iii. 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 infliximab (Remicade®) or golimumab IV (Simponi Aria®)

iv. 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 infliximab (Remicade®)

v. 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 infliximab (Remicade®) or golimumab IV (Simponi Aria®)

vi. For Ankylosing Spondylitis:
1. Infliximab (Remicade®) or golimumab (Simponi Aria®) may be covered
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®) or golimumab IV (Simponi Aria®)

vii. For giant cell arteritis:
1. 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 following criteria are met:
1. Patient has interstitial lung disease, as evidence by high-resolution computed tomography (HRCT)

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: rheumatologist or neurologist
• Systemic sclerosis-associated interstitial lung disease: must be prescribed by, or in consultation with, a pulmonologist or rheumatologist

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

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 3 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 5 to 17 years of age who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
1. Documented hemodialysis for at least 8 weeks
2. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least 8 weeks prior to initiation of therapy
3. Documented stable hemoglobin (HGB) levels for at least 8 weeks prior to initiation of therapy.

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

NPLATE - MEDICAL BENEFIT

MEDICATION(S)
NPLATE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For immune thrombocytopenia,
Initial authorization all of the following must be met:
1. A diagnosis of immune thrombocytopenia (ITP), AND
2. Patient is at risk for bleeding with a platelet count of less than or equal to 30,000 cells per microliter, AND
3. Treatment by at least one of the following was ineffective or not tolerated:
a. Systemic corticosteroids, OR
b. Immune globulin, OR
c. Splenectomy

Reauthorization will require submission of platelet values demonstrating a response to therapy and a weekly dose below 10 microgram/kg.

For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], all of the following must be met:
1. Documentation of acute exposure to radiation, AND
2. Documentation of myelosuppression defined as leukopenia, thrombocytopenia, or anemia

QUANTITY LIMITS:
Nplate is available as 125-, 250-, and 500- mcg single-dose vials of lyophilized powder. Quantity approved may be rounded down to nearest available vial size within 10% of calculated dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist, hematologist, or hepatologist.

COVERAGE DURATION
Initial authorization will be approved for up to three (3) months. Reauthorization will be approved for up to

six (6) months.

OTHER CRITERIA

N/A

OPHTHALMIC VEGF INHIBITORS_MEDICARE PART B

MEDICATION(S)
BEOVU, EYLEA, LUCENTIS, MACUGEN

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 with the requested medication (new start): Must have one (1) of the following diagnoses and meet any required criteria:
a. Neovascular (wet) age-related macular degeneration (AMD):
i. For aflibercept (Eylea®):
1. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contradictions to bevacizumab include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome), or rationale is provided why therapy with bevacizumab is not appropriate for the patient
ii. For ranibizumab (Lucentis®), pegaptanib (Macugen®) and brolucizumab (Beovu®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient

b. Diabetic macular edema or Diabetic retinopathy
i. For aflibercept (Eylea®), one of the following:
1. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contraindications include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome), or
2. Patient’s baseline visual acuity is 20/50 or worse, or
3. Rationale is provided why therapy with bevacizumab is not appropriate for member
ii. For ranibizumab (Lucentis®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member

c. Macular edema following retinal vein occlusion
i. For aflibercept (Eylea®):
1. Documentation that bevacizumab has been ineffective, not tolerated/contraindicated, or rationale is provided why therapy with bevacizumab is not appropriate for the patient

ii. For ranibizumab (Lucentis®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated/ contraindicated, or rationale is provided why therapy is not appropriate for the patient

d. Myopic Choroidal Neovascularization (mCNV): ranibizumab (Lucentis®) may be covered

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)

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

EXCLUSION CRITERIA
1. Patients with a history of liver transplant
2. Patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2

REQUIRED MEDICAL INFORMATION
1. For initiation of therapy (new starts), all of 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 3 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 3 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 3 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

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 of the following must be met:
a. Member is within 100 days post- allogeneic transplant, and
b. Cytomegalovirus (CMV) Recipient positive, and
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 (e.g. antithymocyte globulin (ATG), antithymocyte globulin equine (ATGAM), antithymocyte globulin rabbit (thymoglobulin), alemtuzumab, fludarabine) within the previous 6 months
iii. Transplant was a cord blood allograft
iv. History of CMV drug resistance within the past 6 months
d. Medical rationale provided for not using oral formulation (e.g. 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

PROPYLACTICE 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. Documentation of one of the following clinical criteria:
i. Self-limiting, non-inflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
ii. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
iii. Recurrent laryngeal edema AND

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, AND

c. One of the following:
i. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show both of the following:
1. C4 is less than 50 percent of the lower limit of normal, and
2. One of the following:
a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
b. C1-INH function is 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, KNG1 gene mutation, or
2. Positive family history for HAE AND attacks 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

Cinryze®: 16 vials (500 units each vial) for 28 days
Dosing regimens beyond quantity limits will only be approved if evidence-based-rationale is provided.

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

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 25 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®, and Ventavis®: Class III or IV

ii. Tyvaso®: Class III or IV

iii. Remodulin® 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

Initial authorization for 12 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

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 of the following criteria 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 2 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 slowing of disease progression or stabilization of functional ability and maintenance of activities of daily living (ADLs)
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 and reauthorization will be approved for six months.

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 seven (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 that patient is transfusion-dependent, defined as receiving at least 6-20 units RBC transfusions every 24 weeks
3. Documented baseline Hgb level of at least 9 g/dL, drawn within the previous 30 days

For continuation of therapy for beta-thalassemia beyond 9 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. Diagnosis of MDS with ring sideroblasts (MDS-RS), or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
2. Score of very low to intermediate risk based on the Revised International Prognostic Scoring System
3. Documentation that patient requires RBC transfusions of at least two (2) units every eight (8) weeks
4. One of the following:
a. Documented trial and failure [of at least two (2) months], intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin)
b. Documentation of endogenous erythropoietin level greater than 500 mU/mL

For reauthorization for MDS-RS: 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 9 weeks. Reauthorization will be for one (1) year.
MDS-RS: Initial authorization will be for 6 months. Reauthorization will be for one (1) year

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. Must meet criteria for specific indications, as outlined below: i. For Oncologic diagnoses: For initial authorization: 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 (1) of the following targeted immune modulators: etanercept (Enbrel®), adalimumab (Humira®), a preferred infliximab product or intravenous golimumab (Simponi® Aria), 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) (e.g., leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.

iii. For Vasculitis – including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [e.g., 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 (e.g., 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 (1) of the following:
1. Documentation of trial, failure, or intolerance to at least two (2) 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 (2) of the following conventional therapies:
a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
b. Corticosteroids (e.g., prednisone, methylprednisolone)
c. Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate)
d. Plasma exchange

vii. For Autoimmune Hemolytic Anemia (AIHA):
1. In patients diagnosed with warm AIHA: Documentation of trial, failure, intolerance, or contraindication to glucocorticoids, OR
2. In patients diagnosed with cold AIHA or cold agglutinin disease

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, an oncologist, 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 for one year.

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
For initial authorization:
1. Confirmed diagnosis of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) by one of the following:
a. Gene sequencing showing an FECH, CLPX, or ALAS2 mutation
b. Elevated total erythrocyte protoporphyrin greater than 80 mcg/dL
c. Erythrocyte fractionation shows more than 50% metal-free vs. zinc protoporphyrin
2. Documentation of characteristic symptoms of EPP/XLP phototoxicity (e.g., intolerance to light with symptoms including itching, burning, pain, erythema, or scarring of the skin on contact with sunlight)
3. Documentation that sun avoidance and use of sunscreen and protective clothing have proven inadequate in controlling EPP/ XLP -associated painful skin reactions
4. Documentation that the condition is having a significant impact on quality of life (QOL)

For reauthorization:
1. 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
2. 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, e.g. 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
N/A

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 (1) of the following:
a. Transfusion dependence (eg. 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 (eg. 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 (i.e. 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 of the following must be met:
i. Diagnosis of NMOSD as defined as the following:
1. Presence of at least one core clinical characteristic (i.e., 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 (e.g., Multiple Sclerosis)
iii. Trial and failure, intolerance or contraindication to rituximab
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 (i.e., 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 aHUS: Prescribed by an hematologist/oncologist or nephrologist
MG or NMOSD: Prescribed by a neurologist

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

OTHER CRITERIA
N/A

SOMATOSTATIN ANALOGS - MEDICARE PART B

MEDICATION(S)

SANDOSTATIN LAR DEPOT, SOMATULINE DEPOT

COVERED USES

All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit. The following compendia supported indications may be approved subject to criteria: Acquired immunodeficiency syndrome (AIDS)-related diarrhea, chemotherapy-induced diarrhea, oncologic conditions.

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 (e.g., onasemnogene abeparvovec)
2. Use in combination with risdiplam (Evrysdi®)
3. Advanced symptoms of SMA (e.g., 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 of 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 initial authorization for treatment-resistant depression (TRD), all of the following criteria must be met:
1. Individual has been diagnosed with treatment-resistant depression (TRD) by a psychiatrist within the previous three months. Clinical documentation must be provided that outlines the patient evaluation, plan for on-going management, and treatment options reviewed.
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. Individual has tried and failed three oral antidepressants in at least two different therapeutic classes for at least eight weeks of treatment at the highest tolerable dose or the FDA-approved maximum dose for the medication. Trials should have occurred within the previous two years
4. Individual has tried and failed 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). Trial should have occurred within the previous two years
5. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy

6. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For reauthorization, all of the following criteria must be met:
1. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline depression rating scores
2. Documentation of on-going management with a psychiatrist at minimum of every three months
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For initial authorization for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior all of the following criteria must be met:
1. Individual has been diagnosed with depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior by a psychiatrist
2. Baseline score from one of the following standardized depression rating scales confirming severe depression:
a. PHQ-9 score of at least 20
b. MADRS total score of at least 28
c. HAMD 17 score of at least 24
d. QIDS-C 16 score of at least 16
3. Individual received standard of care treatment including one of the following:
a. Initiation of an antidepressant, or
b. Optimized oral antidepressant, or
c. Added augmentation therapy to current antidepressant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For continuation of care post initiation in inpatient setting all of the following criteria must be met:
1. Documentation of the number of doses provided in the inpatient setting
2. Documentation of clinical improvement in depression symptoms as measured by a clinically significant decrease in baseline depression rating scores
3. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy
4. 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. The administration/monitoring of this product may be completed by any mental health provider.

COVERAGE DURATION

For treatment resistant depression: Initial authorization will be approved for three months. Reauthorization will be approved for six months.

For Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior: Initial authorization will be approved for one month or the remainder of weeks to one month of treatment post inpatient initiation. Reauthorization will only be approved for treatment resistant depression criteria.

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
N/A

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 by one (1) of the following:
a. Sight-threatening disease (e.g., dysthyroid optic neuropathy, corneal breakdown)
b. Eye disease significantly impacts quality of life and at least two (2) of the following:
i. Lid retraction of at least 2 mm, marginal reflex distance-1 (MRD1) greater than four (4), or presence of lagophthalmos
ii. Moderate or severe soft-tissue involvement (e.g. swelling or redness of the eyes)
iii. Inconstant diplopia (i.e., diplopia at extremes of gaze) or constant diplopia (i.e., continuous diplopia in primary or reading position)
2. Documentation of active disease, defined as a Clinical Activity Score of at least three (3)
3. Laboratory evidence of euthyroid state
4. Inadequate response to at least two (2) weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) or inability to use this therapy (e.g., evidence of recent viral hepatitis, significant hepatic dysfunction, severe cardiovascular morbidity or psychiatric disorders) or documentation that patient has sight threatening disease (defined as presence of direct optic neuropathy or corneal breakdown)

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 (6) months for a total of eight (8) infusions

OTHER CRITERIA

N/A

TESTOSTERONE_AVEED_TESTOPEL_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

TOTAL PARENTERAL NUTRITION (TPN)- MEDICARE PART B

MEDICATION(S)

AMINOSYN, AMINOSYN II, AMINOSYN M, AMINOSYN 7%-ELECTROLYTE SOL, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E, CLINIMIX N14G30E, CLINISOL, CLINOLIPID, FREAMINE HBC, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, SYNTHAMIN 17 WITHOUT ELTYE, TRAVASOL, TROPHAMINE

COVERED USES

All Medically-Accepted Indications

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 of a medical condition which does not allow for absorption of sufficient nutrients to maintain weight and strength

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. One of the following:

a. Documentation of failure or contraindication (such as structural or functional bowel disease, e.g., massive small bowel resection, short bowel syndrome) to enteral nutrition

OR

b. Provider attestation that adequate nutrition is not possible by altering the nutrient composition of the enteral diet alone

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 3 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
• Hereditary transthyretin-medicated amyloidosis with cardiomyopathy
• Others forms of amyloidosis that is not due to a genetic mutation in the TTR gene
• Patients without the presence of polyneuropathy symptoms associated with hATTR amyloidosis
• Patients with type I or type II diabetes
• Previous organ transplant(s) requiring immunosuppression
• Malignancy within the past five years
• Uncontrolled cardiac arrhythmia or unstable angina

REQUIRED MEDICAL INFORMATION
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. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
AND
6. 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])
AND

7. For patisiran (Onpattro®): Not taking in combination with inotersen (Tegsedi®) or tafamidis
OR
For inotersen (Tegsedi®): Not taking in combination with patisiran (Onpattro®) or tafamidis

Reauthorization:
1. Documentation that patient is tolerating applicable gene therapy (i.e. inotersen (Tegsedi®) or patisiran (Onpattro®))
AND
2. Documented improvement or stabilization in polyneuropathy symptoms, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures:
3. Baseline polyneuropathy disability (PND) score
4. Familial amyloid polyneuropathy (FAP) stage
5. Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

QUANTITY LIMIT:
For inotersen (Tegsedi®): 4 syringes per 28 days
For patisiran (Onpattro®): See Appendix B

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 6 months
Reauthorization will be approved for 12 months

OTHER CRITERIA
Medicare Part B: Onpattro® Only

TROGARZO - MEDICARE PART B

MEDICATION(S)
TROGARZO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization:
1. Inadequate response to six (6) months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last eight (8) 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 (3) 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 Trogarzo™

Re-authorization or continuation of therapy:
1. Patient has previously received treatment with Trogarzo™.
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 Trogarzo™

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 6 months and reauthorization will be approved for one (1) 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
N/A

REQUIRED MEDICAL INFORMATION
Paroxysmal Nocturnal Hemoglobinuria (PNH):
Initial authorization all of the following must be met:
1. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two (2) independent flow cytometry reagents on at least two (2) 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
2. Severe disease as indicated 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
AND
3. Dose and frequency is in accordance with FDA-approved labeling

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:
1. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1 above) and severe disease (criteria 2 above). However, this can be based on patient's history prior to starting eculizumab.
AND
2. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization:

1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms
2. Dose and frequency is in accordance with FDA-approved labeling

Compliment-Mediated Hemolytic Uremic Syndrome (HUS)
Initial authorization all of the following must be met:
1. Diagnosis of non-infectious HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)
AND
2. 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)
AND
3. Compliment dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD), the activator genes: factor B (CFB) and C3 and autoantibodies to CFH)
AND
4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions) OR medical rationale of why plasma therapy is not appropriate for member
AND
5. Dose and frequency is in accordance with FDA-approved labeling

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®)
1. Confirmed documentation of Compliment-Mediated Hemolytic Uremic Syndrome (criteria 1, 2 and 3 above). However, this can be based on patient's history prior to starting eculizumab.
AND
2. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for HUS:
1. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
• Maintenance of platelet counts (i.e. improvements or reductions less than 25%)
• Reductions in LDH
• Reduction in number of needed plasmaphoresis or plasma infusion events
• Improvement in kidney function and reduction of dialysis
2. Dose and frequency is in accordance with FDA-approved labeling

AGE RESTRICTION
For PNH: Approved for 18 years of age and older
For aHUS: No age restriction

PRESCRIBER RESTRICTION

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

COVERAGE DURATION

Initial authorization for up to 3 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

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 (2) treatment cycles (four (4) injections) will require documentation that

the curvature of the penis remains greater than 15 degrees

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For Dupuytren’s contracture: Authorization will be approved for three (3) months for a maximum of two (2) treatment courses.
For Peyronie’s disease: Initial authorization will be approved for three (3) months, not to exceed four (4) injections. Reauthorization will be approved for six (6) months, not to exceed eight (8) injections per lifetime.

OTHER CRITERIA
N/A

XOLAIR - MEDICARE PART B

MEDICATION(S)
XOLAIR

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

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 (e.g., 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