Medical Benefit Drug Prior Authorization Criteria

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This is a complete list of drugs that have written coverage determination policies. Drugs on this list do not indicate that this particular drug will be covered under your medical or prescription drug benefit. Please verify drug coverage by checking your formulary and member handbook. Additional restrictions and exclusions may apply. If you have questions, please contact Providence Health Plan Customer Service at 503-574-7500 or 1-800-878-4445 (TTY: 711). Service is available five days a week, Monday through Friday, between 8 a.m. and 6 p.m.
ACUTE HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)
BERINERT, KALBITOR, RUCONEST

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria (1-2) must be met:
1. Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:
   a. For HAE Type I and Type II, documentation of the following (per laboratory standard):
      i. Serum C4 below the lower limit of normal,
      AND
      ii. One of the following:
         1. C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or
         2. C1-INH function less than 50 percent of the lower limit of normal
   b. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII), ANGPT1, PLG, or KNG1 gene mutation
      OR
      ii. Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids.
2. For coverage of Berinert®, Kalbitor®, Firazyr®, or Ruconest®: Documentation of trial and failure or contraindication to generic icatibant

For patients established on the requested therapy, all of the following criteria (1-2) must be met:
1. Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE attack episodes.
2. For coverage of Firazyr®: Documentation of trial and failure or contraindication to generic icatibant

For quantities exceeding the formulary quantity limit: Documentation of frequent HAE attacks defined as greater than or equal to two attacks per month on average.

AGE RESTRICTION
Kalbitor® - 12 years and older
Firazyr® - 18 years and older
Ruconest® - 13 years and older
PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an immunologist or an allergist.

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

OTHER CRITERIA
N/A
MEDICATION(S)
ADAKVEO

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with voxelotor (Oxbryta®)

REQUIRED MEDICAL INFORMATION
Initial authorization:
1. Confirmed medical history or diagnosis of sickle cell disease
2. Patient has experienced at least two (2) sickle cell-related pain crises in the prior year
3. Documentation that patient meets one of the following:
   a. 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
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) months
   c. 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)

Reauthorization: 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 1 year

OTHER CRITERIA
N/A
ALPHA-1 PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of:
1. One of the following:
   a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 micromol/L (approximately 50 mg/dL by nephelometry or 80mg/dL by immunodiffusion)
   b. Patient has one of the following high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null)
   AND
2. Diagnosis of emphysema with one of the following:
   a. Forced expiratory volume per one second (FEV-1) of 35 to 65% of predicted volume
   b. Rapid lung function decline as evidence by reduction of FEV-1 of 100 mL/year or greater
   AND
3. Documentation that the patient has never smoked or has abstained from smoking for at least the previous six months

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

QUANTITY LIMIT:
60 mg/kg infused every seven days, subject to audit.
Note: Dose may be rounded down to the nearest gram (500 mg for Aralast®) within 10% of calculated dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Initial authorization will be approved for six months and reauthorization will be approved for one year.

OTHER CRITERIA
N/A
ANTI-AMYLOID MONOCLONAL ANTIBODIES

MEDICATION(S)
ADUHELM, LEQEMBI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Commercial/Medicaid:
Monoclonal antibodies directed against amyloid is not considered medically necessary and will not be covered due to insufficient evidence of a clinical benefit and safety concerns.

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
N/A

OTHER CRITERIA
N/A
BENLYSTA

MEDICATION(S)
BENLYSTA 120 MG VIAL, BENLYSTA 400 MG VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
Belimumab will not be approved if any of the following are present:
1. Severe active central nervous system lupus
2. Current use of other biologic immunomodulator
3. Documentation of previous use of dialysis in the past 12 months or currently using dialysis
4. Concurrent use of voclosporin (Lupkynis®) or anifrolumab (Saphnelo®)

REQUIRED MEDICAL INFORMATION
For patients initiating therapy for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all the following must be met:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist
AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
   c. Positive anti-Smith (Anti-Sm)
   d. Positive anti-Ro/SSA and anti-La/SSB antibodies
AND
3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
   a. For SLE without Active Lupus Nephritis:
      i. Oral corticosteroid(s)
      ii. Azathioprine
      iii. Methotrexate
      iv. Mycophenolate mofetil
      v. Hydroxychloroquine
      vi. Chloroquine
vii. Cyclophosphamide
b. For SLE with Active Lupus Nephritis:
   i. mycophenolate for induction followed by mycophenolate for maintenance, OR
   ii. cyclophosphamide for induction followed by azathioprine for maintenance.
4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

For patients established on therapy, the following criteria must be met:
1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events)
2. Patient currently receiving standard therapy for SLE and active lupus nephritis

AGE RESTRICTION
Age five years and older for IV infusion
Age 18 years and older for subcutaneous injection

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

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

OTHER CRITERIA
N/A
BOTULINUM TOXIN

MEDICATION(S)
BOTOX, BOTOX COSMETIC, DYSPORT, JEUVEAU, MYOBLOC, XEOMIN

COVERED USES
N/A

EXCLUSION CRITERIA
• When the above criteria are not met, botulinum toxin is considered investigational and not covered.
• Botulinum toxin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face.
  o PrabotulinumtoxinA (Jeuveau®) will not be covered as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.

REQUIRED MEDICAL INFORMATION
OnabotulinumtoxinA (Botox®) may be covered for the following indications when criteria are met:
1. Chronic migraine headaches in adults when all of the following is met:
   a. Documentation of at least 15 headache days per month with headaches lasting four hours or longer
   b. Documentation of trial and failure, intolerance, or contraindication to at least TWO of the following classes used for migraine prevention. Trial and failure is defined as inadequate response following a minimum three months of consistent use.
      i. Antidepressants (e.g., amitriptyline, venlafaxine)
      ii. Beta-blockers (e.g., metoprolol, propranolol, timolol)
      iii. Antiepileptics (e.g., divalproex, valproate, topiramate)
   c. For patients established on a Calcitonin Gene Related Peptide (CGRP) receptor antagonist for migraine prophylaxis, combination therapy with Botox® may be considered medically necessary if the following criteria are met:
      i. The patient has been established on, and adherent to, CGRP prophylaxis therapy (i.e., Aimovig®, Emgality®, Ajovy®) for at least six months and has a documented improvement in frequency and/or severity of migraine headaches
      ii. Patient continues to have at least 15 headache days per month with headaches lasting four hours or longer, despite use of CGRP prophylaxis monotherapy
   d. Reauthorization for Botox® monotherapy or combination therapy with CGRP for prophylaxis will require documentation of a 30% reduction in headache days from baseline.
2. Spasticity in patients at least two years of age
3. Cervical dystonia in adults
4. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
5. Severe axillary hyperhidrosis in adults after documented trial and failure, intolerance or contraindication
to topical agents
a. Note: The safety and effectiveness of onabotulinumtoxinA for hyperhidrosis in other body areas have not been established.

6. Overactive bladder in adults with:
a. Symptoms of urge urinary incontinence, urgency, and frequency
b. Documented trial and failure, intolerance, or contraindication to at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)

7. Urinary incontinence in patients at least five years of age:
a. Due to detrusor over activity related to a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
b. Documented trial and failure, intolerance, or contraindication at least one month of anticholinergic medication (e.g., oxybutynin, tolterodine)

8. Excessive salivation due to advanced Parkinson’s disease

9. Hemifacial spasm

10. Chronic anal fissure when all of the following is met:
a. Prescribed by, or in consultation with, a gastroenterologist or colorectal surgeon
b. Documentation of trial and failure, intolerance, or contraindication to at least six weeks of therapy with either topical nitrates or topical calcium channel blockers
c. One of the following:
   i. Documentation that the patient is not a good candidate for surgery or appropriate medical rationale is provided for avoiding surgery
   ii. Botox® is to be used in conjunction with fissurotomy
d. The use of Botox® in combination with sphincterotomy or anal advancement flap is considered experimental and investigational and will not be covered

11. Spastic dysphonia (laryngeal dystonia) for adductor type when prescribed by, or in consultation with, a specialist in laryngology

12. Achalasia in patients ineligible for definitive treatments, such as pneumatic dilation, surgical myotomy or peroral endoscopic myotomy (POEM)
a. The use of Botox® in combination with pneumatic dilation is considered experimental and investigational and will not be covered

AbobotulinumtoxinA (Dysport®) may be covered for the following indications:
1. Spasticity in patients two years of age and older
2. Cervical dystonia in adults
3. Blepharospasm in adults

IncobotulinumtoxinA (Xeomin®) may be covered for the following indications:
1. Chronic sialorrhea in patients two years and older
2. Upper limb spasticity in patients at least two years of age
3. Cervical dystonia in adults
4. Blepharospasm in adults
RimabotulinumtoxinB (Myobloc®) may be covered for the following indications:
1. Cervical dystonia in adults
2. Chronic sialorrhea in adult 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
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 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 12 years and older

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

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

OTHER CRITERIA
N/A
CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS

**MEDICATION(S)**
VYEPTI

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
• Concomitant use of CGRP agent for migraine prophylaxis with botulinum toxin for cluster headaches or migraine headaches that do not meet criteria outlined above

**REQUIRED MEDICAL INFORMATION**
1. For initial authorization, the following indication-specific criteria must be met:
   a. For migraine prophylaxis (chronic and episodic), Emgality®, Aimovig®, Ajovy®, Vyepti®, Nurtec ODT®, or Quilpta® may be covered if the following criteria are met:
      i. Diagnosis of migraine headaches with at least four headache days per month, AND
      ii. One of the following:
         1. Trial and inadequate response to a trial of at least one prophylactic medication from one of the following categories. Trial must be at least six weeks (while adherent to therapy) at an appropriate dose for migraine prophylaxis:
            a. Anticonvulsants, specifically divalproex, valproate, or topiramate
            b. Beta-blockers, specifically metoprolol, propranolol, or timolol
            c. Antidepressants, specifically amitriptyline or venlafaxine
      iii. The patient has been evaluated for, and does not have, medication overuse headache
   iv. For non-preferred CGRP prophylactic agents (Vyepti®): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig®, Emgality®, Quilpta®, Nurtec ODT®, or Ajovy®)
   v. The patient will NOT be using the requested agent in combination with another prophylactic CGRP
   vi. For patients established on botulinum toxin for migraine prophylaxis, combination therapy may be considered medically necessary if the following criteria are met:
      1. 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
      2. 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
      3. Combination therapy is prescribed by, or in consultation with, a neurologist
   b. For episodic cluster headaches, Emgality® may be covered if all the following criteria are met:
      i. A history of at least five cluster headache attacks, with at least two of the cluster periods lasting at least
seven days,
ii. Cluster periods are separated by at least three months of pain-free remission,
iii. One of the following:
   1. Inadequate response to at least six weeks trial (while adherent to therapy) of at least one of the following:
      a. Verapamil
      b. Melatonin
      c. Lithium
      d. Topiramate
   2. Documented intolerance or contraindication to all of the therapies listed above,
iv. The patient has been evaluated for, and does not have, medication overuse headache
c. For the acute treatment of migraine headaches, Nurtec ODT® or Ubrelvy® may be covered if the following criteria are met:
i. One of the following:
   1. Inadequate response or intolerance to two triptan drug entities (such as sumatriptan, zolmitriptan, naratriptan, almotriptan, eletriptan, frovatriptan, rizatriptan)
   2. Documented intolerance to at least two triptan drug entities
   3. Documented contraindication to the use of triptans, such as:
      a. Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal’s angina)
      b. History of stroke or transient ischemic attack (TIA)
      c. Peripheral vascular disease
      d. Ischemic bowel disease
      e. Uncontrolled hypertension
      f. History of hemiplegic or basilar migraine
   ii. The patient will NOT be using the requested agent in combination with another acute migraine therapy (such as triptan, ergotamine, or acute use CGRP)
   iii. For Ubrelvy®: Inadequate response or intolerance to rimegepant (Nurtec ODT®)
2. For patients established on the requested therapy, the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy:
   a. For migraine prophylaxis:
      i. Documented reduction in the severity or frequency of headaches.
      ii. The patient will NOT be using the requested agent in combination with another prophylactic CGRP
   b. For acute treatment of migraines:
      i. Documentation of treatment success, as demonstrated by a reduction of migraine pain or freedom from migraine symptoms
      ii. The patient will NOT be using the requested agent in combination with another acute use CGRP
3. For quantity limit exception requests:
   a. For migraine prophylaxis: doses above the FDA maximum recommended dose will not be covered.
i. Nurtec ODT® will be allowed at a quantity of 18 tablets per 30 days if coverage for migraine prophylaxis is approved.

b. For acute treatment of migraines:

i. The safety and efficacy of treating more than eight migraine headaches per month with ubrogepant (Ubrelvy®) has not been established, quantities to treat more than eight migraine headaches (16 tablets) will not be covered.

ii. Quantities of up to 18 tablets per month of rimegepant (Nurtec ODT®) may be covered for acute treatment if the patient is on prophylactic therapy with a non-CGRP agent (e.g., divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, or venlafaxine) and the patient is still experiencing more than two headache days per week.

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
CONSTIPATION AGENTS

MEDICATION(S)
RELISTOR 12 MG/0.6 ML SYRINGE, RELISTOR 12 MG/0.6 ML VIAL, RELISTOR 8 MG/0.4 ML SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent.

2. For all requests, medication will not be used concomitantly with other intestinal secretagogues, selective 5-HT agonists or peripherally acting mu-opioid receptor antagonists covered by this policy.

3. For patients already established on the requested product (Note: medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
   i. Documentation of response to therapy (such as less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools).

4. For patients not established on the requested product must meet ALL the following indication-specific criteria:
   i. For chronic idiopathic constipation (CIC):
      a. Documentation of two or more of the following occurring over the last three months:
         1) Fewer than three spontaneous bowel movements per week
         2) Straining during defecations
         3) Lumpy or hard stools (Bristol Stool Form Scale 1-2)
         4) Sensation of incomplete evacuation
         5) Sensation of anorectal obstruction/blockage
         6) Manual maneuvers to facilitate defecations (e.g., digital evacuation, support of the pelvic floor)
   b. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
   c. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL the following:
      1) Regular use of dietary fiber supplementation (e.g., cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids),
2) A stimulant laxative (e.g., senna, bisacodyl)
3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (e.g., lactulose, Miralax®)
4) Lubiprostone (Amitiza®)

ii. For irritable bowel syndrome with constipation (IBS-C):
   a. Documentation of recurrent abdominal pain occurring, on average, at least one day per week during the previous three months with two or more of the following criteria:
      1) Related to defecation (either increased or improved pain)
      2) Associated with a change in stool frequency
      3) Associated with a change in stool form (appearance)
   b. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL the following:
      1) Regular use of dietary fiber supplementation (e.g., cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids)
      2) Routine laxative therapy with polyethylene glycol (Miralax®)
   c. For Zelnorm®: patient is a woman aged 65 years or younger without contraindication to therapy.
      Contraindications include:
      1) History of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina
      2) History of ischemic colitis or other forms of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesion
      3) Moderate or severe hepatic impairment
      4) Severe renal disease or end-stage renal disease
   d. For Ibsrela®: Failure, contraindication, or intolerance to one of the following medications:
      1) Lubiprostone (Amitiza®)
      2) Linaclotide (Linzess®)

iii. For opioid-induced constipation (OIC):
   a. Patient is on chronic opioid therapy
   b. Documentation of less than three spontaneous bowel movements per week
   c. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL the following:
      1) A stimulant laxative (e.g., senna, bisacodyl)
      2) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g., lactulose, Miralax®)
   d. For Relistor®: Failure, contraindication, or intolerance to one of the following medications:
      i. Naloxegol (Movantik®)
      ii. Lubiprostone (Amitiza®)
      iii. Naldemedine (Symproic®)
AGE RESTRICTION
Ibsrela® may be approved for patients aged 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For OIC: Initial authorization will be approved for six months. Reauthorization will be approved for one year

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

OTHER CRITERIA
N/A
CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE

MEDICATION(S)
DEXCOM G4 RECEIVER, DEXCOM G4 TRANSMITTER, DEXCOM G5 RECEIVER, DEXCOM G5 TRANSMITTER, DEXCOM G5-G4 SENSOR, DEXCOM G6 RECEIVER, DEXCOM G6 SENSOR, DEXCOM G6 TRANSMITTER, DEXCOM RECEIVER, FREESTYLE LIBRE 14 DAY READER, FREESTYLE LIBRE 14 DAY SENSOR, FREESTYLE LIBRE 2 READER, FREESTYLE LIBRE 2 SENSOR, FREESTYLE LIBRE 3 SENSOR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Continuous glucose monitors may be considered medically necessary and covered for the management of insulin-dependent diabetes when all the following criteria are met:
A. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and
B. The patient is currently using insulin therapy. This may be verified by pharmacy claim(s) for insulin within the previous 120 days.
II. Continuous glucose monitors may be considered medically necessary and covered for patients experiencing post-bariatric hypoglycemia (PBH) when all the following criteria are met:
C. Other causes of hypoglycemia have been ruled out (such as malnutrition, adverse events from medications, dumping syndrome, or insulinoma), and
D. The patient is experiencing severe hypoglycemia episodes or hypoglycemia unawareness

Replacement of Continuous Glucose Monitors
I. Upgrade or replacement of continuous glucose monitor systems may be considered medically necessary and covered when there is documentation that one or more of the device components meet all of the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and
C. Cannot be repaired.
II. Upgrade or replacement of continuous glucose monitor systems is considered not medically necessary and not covered when criterion II above is not met.

Upon approval, concurrent use of test strips will be limited to:
• Dexcom G6/Dexcom G7/Freestyle Libre 2/Libre 3: 50 test strips per 90-day supply
  o An additional 50 test strips per 90 days may be approved with documentation that the patient has low blood glucose levels requiring verification at least two times per week (See Diabetic DME policy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
CRYSVITA_MEDICAL BENEFIT

MEDICATION(S)
CRYSVITA

COVERED USES
N/A

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

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

For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:
1. Documentation of recent serum phosphorus level and levels have normalized while on therapy, and
2. Documentation of at least one of the following responses to therapy:
a. Improvement in skeletal deformities
b. Healing of fracture or pseudofractures
c. Reduction in number of fractures/pseudofractures
d. Increase in growth velocity, and

3. Documentation of patient’s current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A
MEDICATION(S)
ACCU-CHEK AVIVA PLUS, ACCU-CHEK GUIDE ME GLUCOSE MTR, ACCU-CHEK GUIDE MONITOR SYSTEM, ACCU-CHEK GUIDE TEST STRIP, ACCU-CHEK SMARTVIEW TEST STRIP, ACCUTREND GLUCOSE TEST STRIP, ONETOUCH ULTRA TEST STRIP, ONETOUCH ULTRA2, ONETOUCH VERIO FLEX METER, ONETOUCH VERIO TEST STRIP

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

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

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

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

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
DISPOSABLE INSULIN PUMPS

MEDICATION(S)
OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4)

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
I. Disposable insulin pumps may be considered medically necessary and covered for the treatment of insulin-dependent diabetes when one of the following criteria are met:
A. The request is for a patient with Type 1 diabetes, or
B. All the following:
   1. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and
   2. The patient has been on a program of multiple daily injections of insulin (at least two injections per day), and
   3. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (four or more blood glucose readings per day or use of continuous glucose monitor) and patient has any of the following problems controlling blood glucose level:
      i. Documented hypoglycemia unawareness, or
      ii. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or
      iii. Glycosylated hemoglobin level (HbA1C) greater than 7%, or
      iv. History of recurring, symptomatic hypoglycemia, or
      v. Fasting blood sugars frequently exceeding 200 mg/dL, or
      vi. History of severe glycemic fluctuations, or
      vii. Documented need for more than five daily injections of insulin.
B. For requests for V-go: failure of Omnipod or medical rationale provided for use of this pump over Omnipod

Replacement of Disposable Insulin Pumps
II. Upgrade or replacement of existing insulin pump may be considered medically necessary and covered when there is documentation that one or more of the device components meet all the following criteria (A.-C.):
A. Are no longer functional, and
B. Are not under warranty, and
C. Cannot be repaired.

III. Upgrade or replacement of existing insulin pump is considered not medically necessary and not covered when criterion II above is not met.

Note: The Omnipod pump Personal Diabetes Manager (PDM) is supplied by the manufacturer for most Commercial patients, so patients should be referred to Insulet Corporation for free starter kit or for replacement at 1-800-591-3455.

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
MEDICATION(S)
DURYSTA

COVERED USES
N/A

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 (for example, bimatoprost, latanoprost, or travoprost)

AGE RESTRICTION
Approved for 18 years and older

PRESCRIBER RESTRICTION
Must be prescribed by an ophthalmologist

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

OTHER CRITERIA
N/A
EMPAVELI

MEDICATION(S)
EMPAVELI

COVERED USES
N/A

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

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

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

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

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

**OTHER CRITERIA**
N/A
**ENJAYMO**

**MEDICATION(S)**
ENJAYMO

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

For patients that are established on therapy, all the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Diagnosis of cold agglutinin disease
2. Documentation of successful response to therapy defined as an increase in hemoglobin level or reduced transfusion requirements
3. Dose and frequency are in accordance with FDA-approved labeling

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

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

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved for a year.
OTHER CRITERIA
N/A
ENZYME REPLACEMENT THERAPY_MEDICAL BENEFIT

MEDICATION(S)
ALDURAZYME, BRINEURA, CEREZYME, ELAPRASE, ELEYSO, FABRAZYME, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, VIMIZIM, VPRIV, XENPOZYME 20 MG VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

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

1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms).
   a. For olipudase alfa (Xenpozyme®) only, documentation of improvement in at least one of the following: spleen volume, liver volume, platelet count, DLco or forced vital capacity (FVC)
   b. For cerliponase alfa (Brineura®) only, documentation of both of the following:
      i. No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale
      ii. Motor Domain of the CLN2 Clinical Rating Scale score remains above zero

2. Dosing is within FDA-labeled guidelines

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

**AGE RESTRICTION**
Age must be appropriate based on FDA-approved indication

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

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

**OTHER CRITERIA**
N/A
ERYTHROPOIESIS STIMULATING AGENTS (ESAS)

MEDICATION(S)
ARANESP, EPOGEN, MIRCERA, PROCRIT, RETACRIT

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with uncontrolled hypertension

REQUIRED MEDICAL INFORMATION
For patients initiating therapy:
1. All diagnoses, with the exception of 2e (preoperative use in patients scheduled for elective non-cardiac, nonvascular surgery), must have documented Hemoglobin (HGB) levels of less than or equal to 10g/dl 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. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
   b. Treatment of anemia in patients with cancer:
      i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
      AND
      ii. One of the following clinical scenarios:
          1. Patient has comorbid chronic kidney disease
          2. Patient undergoing palliative treatment
   c. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis
      i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%
      ii. Must have documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL
   d. Anemia associated with zidovudine-treated HIV-infection patients
      i. Documented current (within last three months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
      ii. Zidovudine dose is less than or equal to 4200 mg/week
e. Preoperative use in patients scheduled for elective noncardiac and nonvascular surgery, all of the following criteria must be met:
   i. Member has preoperative HGB between 10 and 13 g/dL
   ii. The surgery has a high-risk for perioperative blood loss (for example, expected to lose more than two units of blood)
   iii. Patient is unwilling to donate autologous blood pre-operatively
f. Mircera only: For the treatment of pediatric patients 5 to 17 years of age who are on hemodialysis and converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
   i. Documented hemodialysis for at least eight weeks
   ii. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy
   iii. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

For patients established on therapy (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
1. Documentation of continued medical necessity (such as ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for one year

OTHER CRITERIA
N/A
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.
REQUIRED MEDICAL INFORMATION
For initiation of therapy for multiple sclerosis (MS), all the following criteria (1-3) must be met:

1. Must have one of the following confirmed diagnoses:
   a. Relapsing-remitting multiple sclerosis (RRMS)
   b. Secondary progressive multiple sclerosis (SPMS)
   c. Clinically isolated syndrome (CIS)

2. Documentation of ONE of the following:
   a. Inadequate response (after at least six months of continuous therapy) or intolerance to generic dimethyl fumarate or generic glatiramer OR
   b. FDA labeled contraindication to BOTH generic dimethyl fumarate and generic glatiramer

3. Documentation of active disease after an adequate trial (defined as at least six months of continuous therapy) of at least one of the following preferred agents unless all are contraindicated OR medical rationale why therapies cannot be tried is provided. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
   b. Interferon-beta 1b (Betaseron®)
   c. Teriflunomide (Aubagio®)
   d. Fingolimod (Gilenya®)
   e. Ozanimod hydrochloride (Zeposia®)
   f. Siponimod (Mayzent®)
   g. Cladribine (Mavenclad®)
   h. Ofatumumab (Kesimpta®)

For patients established on therapy for at least three months, documentation of positive clinical response to therapy must be provided.

Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
AGE RESTRICTION
N/A

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

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

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)
CAMCEVI, ELIGARD, FENSOLVI, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE DEPOT,
LUPRON DEPOT, LUPRON DEPOT-PED, SUPPRELIN LA, TRELSTAR, TRIPTODUR, VANTAS,
ZOLADEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of male infertility

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. For oncological indications, gonadotropin releasing hormone agonists may be covered if the following
criteria are met:
a. Use is for an FDA approved indication or indication supported by National Comprehensive Cancer
Network guidelines with recommendation 2A or higher

2. For uterine leiomyomata (fibroids), leuprolide acetate may be covered if one of the following criteria (a or
b) are met:
a. Request is for use prior to surgery to improve anemia caused by fibroids and one of the following criteria
(i or ii) are met:
i. Request is for a Medicaid member
ii. Both of the following criteria:
   • Documented trial, failure, intolerance, or contraindication to at least 30 days of therapy with iron
     supplementation alone
   • Documentation that leuprolide acetate will be used in combination with iron supplementation
b. Request is for use prior to surgery to reduce the size of fibroids and the following criteria are met:
i. Documentation that surgical removal of fibroids is planned within four months

3. For endometriosis, leuprolide acetate, goserelin acetate, or nafarelin acetate may be covered if the
following criteria (a and b) are met:
a. Documentation that other causes of gynecologic pain have been ruled out (e.g., irritable bowel
syndrome, interstitial cystitis, urinary tract disorders)
b. For Synarel® (nafarelin acetate): Documented trial and failure to leuprolide acetate

4. For endometrial thinning/dysfunctional uterine bleeding, goserelin acetate may be covered if the following
criteria are met:

a. Documentation for use prior to endometrial ablation

5. For central precocious puberty, gonadotropin releasing hormone agonists may be covered if one of the following criteria (a, b, or c) are met:
   a. Request is for a Medicaid member
   b. Request is for a one-time dose for diagnostic purposes
   c. All of the following criteria:
      i. Documentation of a history of early onset of secondary sexual characteristics (age eight years and under for females or nine years and under for males)
      ii. Confirmation of diagnosis by one of the following:
          • 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)]
          • Pubertal level of basal LH levels (0.2 IU/L or greater)
          • Bone age advanced one year beyond the chronological age
      iii. For Synarel®: Documented trial and failure or contraindication/intolerance to both of the following:
          • Leuprolide acetate
          • Triptodur® or Supprelin LA®

6. For gender-affirming services, gonadotropin releasing hormone agonists may be covered if the following criteria (a and b) are met:
   a. Prescribed by or in consultation with an endocrinologist
   b. Demonstration that puberty has progressed to a minimum of Tanner Stage 2

For reauthorization:

1. For oncological indications: Documentation of successful clinical response to therapy
2. For uterine leiomyomata (fibroids): Reauthorization will not be authorized. Initial criteria must be met.
3. For endometriosis:
   a. Leuprolide acetate requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g., norethindrone) to help prevent bone mineral density loss.
   b. For Synarel® and Zoladex®: Reauthorization will not be authorized. Treatment is only recommended for up to six months with these agents for endometriosis.
4. For endometrial thinning/dysfunctional uterine bleeding: Reauthorization will not be authorized. Initial criteria must be met.
5. For central precocious puberty:
   a. Clinical response to treatment such as pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level, and
   b. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression
6. For gender-affirming services: Documentation of successful clinical response to therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Oncological Indications: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
Uterine leiomyomata (fibroids): Initial authorization will be approved for three 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.
Endometrial thinning/dysfunctional uterine bleeding: Initial authorization will be approved for two months. No reauthorization.
Central precocious puberty: Authorization/reauthorization will be approved for one year
Gender-affirming services: Authorization/reauthorization will be approved for one year

OTHER CRITERIA
N/A
HEMGENIX

MEDICATION(S)
HEMGENIX

COVERED USES
N/A

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

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

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

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

COVERAGE DURATION
Authorization will be limited to one treatment course per lifetime.

OTHER CRITERIA
HEMLIBRA_MEDICAL BENEFIT

MEDICATION(S)
HEMLIBRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

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

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A
HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (FH) AGENTS

MEDICATION(S)
EVKEEZA

COVERED USES
N/A

EXCLUSION CRITERIA
1. Concomitant use of therapies on this policy (specifically, Juxtapid or Evkeeza)
2. Current pregnancy
3. Diagnosis of Heterozygous familial hypercholesterolemia or other hyperlipidemia disorders

REQUIRED MEDICAL INFORMATION
For initial authorization, all 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), proprotein convertase subtilisin/kexin type 9 (PCSK9) or LDL receptor adapter protein 1 (LDLRAP1) genes
   b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL or treated LDL-C greater than or equal to 300 mg/dL and one of the following:
      i. Presence of xanthomas before the age of 10 years, or
      ii. Evidence of heterozygous familial hypercholesterolemia in both parents such as documented history of elevated LDL-C greater than or equal to 190 mg/dL prior to lipid-lowering therapy
2. Current use of all of the following therapies:
   a. High-intensity statin therapy, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily, unless contraindicated or documented statin intolerance
   b. Ezetimibe, unless contraindicated or prior intolerance
   c. PCSK-9 inhibitor (such as, evolocumab), unless contraindicated or prior intolerance
3. Documentation of LDL cholesterol levels (taken within the last six months) of greater than 100 mg/dL despite at least six 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
HORMONE REPLACEMENT THERAPY

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 (such as decreased libido, sexual dysfunction)

REQUIRED MEDICAL INFORMATION
Hormone replacement therapy is considered medically necessary if all the following criteria are met:
1. One of the following diagnoses:
   a. Gender dysphoria or gender identity disorder (diagnosis codes F64.0, F64.1, F64.8, or F64.9)
   OR
   b. Diagnosis of primary or secondary (hypogonadotropic) hypogonadism
2. For testosterone replacement: Documented inability to reach therapeutic levels or experiencing fluctuations in levels (resulting in symptoms) of the following:
   a. For topical products: Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump)
   b. For injectable products: Generic injectable testosterone cypionate
   c. For oral products: Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump) AND Kyzatrex® (testosterone undecanoate capsule)
   d. For all other products including pellets and nasal products: Must try two of the following:
      i. Generic formulary topical testosterone (such as generic topical testosterone 1% or generic topical testosterone 1.62% pump)
      ii. Generic injectable testosterone cypionate
      iii. Kyzatrex® (testosterone undecanoate capsule)
3. For estrogen replacement: The use of a subcutaneous pellet formations of estrogen is considered investigational for all indications.

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
IL-5 INHIBITORS

MEDICATION(S)
CINQAIR, FASENRA, NUCALA 100 MG/ML POWDER VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with anti-IL5 (such as mepolizumab, reslizumab, benralizumab), anti-IgE (such as omalizumab), anti-TSLP (such as tezepelumab), or anti-IL4 (such as dupilumab) monoclonal antibodies.

REQUIRED MEDICAL INFORMATION
A. Eosinophilic asthma
   1. For patients initiating therapy for eosinophilic asthma, all the following criteria (a-c) must be met:
      a. Confirmed diagnosis of one of the following (i or ii):
         i. Eosinophilic asthma, defined as one of the following:
            ii. A blood eosinophil count of at least 150 cells/microliter while on high-dose inhaled corticosteroids or daily oral corticosteroids
            iii. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion while on high-dose inhaled corticosteroids or daily oral corticosteroids
            iv. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids
            v. History of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
      b. Documentation of adherence to treatment with maximally tolerated doses of the following medications (this may be verified by pharmacy claims information), unless intolerance or contraindication to all therapies:
         i. Inhaled corticosteroid plus
         ii. One of the following:
            1) A long-acting inhaled beta 2-agonist (LABA)
            2) A leukotriene receptor antagonist (LTRA)
            3) A long-acting muscarinic antagonist (LAMA)
      c. Documentation inadequate asthma control despite above therapy, defined as one of the following:
         i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score more than 1.5
         ii. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
         iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
   For patients established on therapy for eosinophilic asthma: documentation of response to therapy, such as
B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)
1. For patients initiating therapy for EGPA, Nucala (mepolizumab) may be covered if the following criteria are met:
   a. Confirmed diagnosis of EGPA defined as one of the following:
      i. The patient meets four of the following:
         1) Asthma (history of wheezing or diffuse high-pitched rales on expiration)
         2) Eosinophilia (greater than 10% eosinophils on white blood cell differential count)
         3) Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis
         4) Migratory or transient pulmonary infiltrates detected radiographically
         5) Paranasal sinus abnormality
      ii. The patient meets ALL of the following:
         1) Medical history of asthma
         2) Peak peripheral blood eosinophilia greater than 1500 cells/microliter
         3) Systemic vasculitis involving two or more extra-pulmonary organs
   b. Documentation of relapsing or refractory disease defined as one of the following:
      i. 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)
      ii. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering off 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

2. For patients established on therapy for EGPA, Nucala (mepolizumab) may be covered if the following criteria are met: Documentation of response to therapy indicating improvement or stabilization of condition

C. Hypereosinophilic Syndrome (HES)
1. For patients initiating therapy for HES, Nucala (mepolizumab) may be covered if the following criteria are met:
   a. Documentation of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
   b. Blood eosinophil count of 1,000 cells/microliter or higher for at least six months prior to initiation of therapy
   c. Documentation of at least two HES flares in the 12 months prior to initiation of therapy (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
   d. For Commercial: Documentation of use of conventional HES therapy, including one of the following in the
12 months prior to initiation of therapy:
i. Chronic or episodic oral corticosteroids (OCS)
ii. Immunosuppressive therapy
iii. Cytotoxic therapy

2. For reauthorization for HES, Nucala (mepolizumab) may be covered if the following criteria are met:
Documentation of response to therapy indicating improvement or stabilization of condition

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. For patients initiating therapy for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met:
a. Evidence of nasal polyposis by direct examination, endoscopy, or sinus computed tomography (CT) scan
b. Documentation of inadequate response to a three-month trial of intranasal corticosteroids (such as fluticasone) or a documented intolerance or contraindication to ALL intranasal corticosteroids
c. Documentation that patient will continue standard maintenance therapy (such as nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab

2. For reauthorization for CRSwNP, Nucala (mepolizumab) may be covered if the following criteria are met:
Documentation of response to therapy indicating improvement or stabilization of condition

AGE RESTRICTION
• Cinqair®: May be approved for patients 18 years of age or older
• Fasenra®: May be approved for patients 12 years of age or older
• Nucala®: May be approved for patients six years of age or older for eosinophilic asthma, 18 years of age and older for EGPA and CRSwNP, and 12 years of age and older for HES

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

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

Hypereosinophilic Syndrome: Must be prescribed by or in consultation with a hematologist, immunologist, pulmonologist, cardiologist, or neurologist

Chronic Rhinosinusitis with Nasal Polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist

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

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

OTHER CRITERIA
N/A
MEDICATION(S)
ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, Gammagard Liquid, Gammagard S-D, GammakeD, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial Authorization for ALL indications:
1. The medical diagnosis is an FDA approved indication or is listed as a covered medical condition below and any indication specific criteria in the policy is met

AND

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

Re-Authorization for ALL indications:
1. Documentation of response to therapy and any indication specific re-authorization criteria listed below is met

Indication-Specific Requirements:

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

1. The patient has one of the following:
   a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
   b. The patient has abnormal Bruton tyrosine kinase (BTK) gene or absence of BTK protein
   c. The patient has an absence of B lymphocytes
   d. The patient meets all of the following:
      i. One of the following:
         1) The patient has selective IgG subclass deficiency [Defined as deficiency of one or more IgG subclasses
(e.g., IgG1, IgG2, IgG3, or IgG4) more than two standard deviations (SD) below age-specific mean, assessed on two separate occasions during infection free period.

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

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

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

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

Reauthorization:

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

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

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

OR

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

Kawasaki Disease:

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

Idiopathic or Immune Thrombocytopenic Purpura (ITP):

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

For children with ITP:

1. Documentation of one of the following:
   a. Platelet count less than 20,000 and significant mucous membrane bleeding
   b. Platelet count less than 10,000 and minor purpura
   c. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss

Pregnant Women with ITP:

1. Documentation of one of the following:
   a. Platelet count is less than 100,000
   b. Past history of splenectomy
   c. Past history of delivered infant with autoimmune thrombocytopenia
Adult Patients with ITP:
1. Documentation of one of the following:
   a. Platelet count of less than 30,000
   b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding
   c. To defer or avoid splenectomy
   d. Rapid increase in platelets required due to planned surgery, dental extractions, or other procedures likely to cause blood loss (platelet count goal is generally greater than 50,000)
2. Documentation that IGG product will be used in combination with corticosteroid therapy or corticosteroid therapy is contraindicated

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

Reauthorization: Documented response to therapy

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

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

Guillain-Barre Syndrome:
1. Documentation that symptom onset is within two weeks or symptoms are severe (such as being unable to ambulate independently)
AND
2. Documented trial, failure, intolerance or contraindication to plasma exchange

Multifocal motor neuropathy:
1. Confirmed diagnosis: motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities
AND
2. Documentation of severe disease/disability

Multiple Sclerosis:
1. Documentation of relapsing/remitting disease
AND
2. Documented trial, failure, intolerance or contraindication to at least two conventional therapies (such as glatiramer, interferon beta, dimethyl fumarate)

Myasthenia Gravis:
Myasthenic exacerbation:
1. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month:
   a. Difficulty swallowing
   b. Acute respiratory failure
   c. Major functional disability responsible for the discontinuation of physical activity

Refractory disease:
1. Documentation that patient has severely impaired function due to myasthenia gravis
AND
2. Documented trial, failure, intolerance or contraindication to at least two of the following conventional therapies:
   a. Acetylcholinesterase inhibitors (such as pyridostigmine)
   b. Corticosteroids (such as prednisone, methylprednisolone)
   c. Immunosuppressive agents (such as azathioprine, cyclosporine, mycophenolate)
   d. Plasma exchange

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:
1. Documentation of one of the following:
   a. Therapy is requested for use within 100 days after transplantation (transplantation date must be documented)
   OR
   b. Documentation that patient has an IgG less than 400 mg/dL with a history of recurrent infections
Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis
1. Documentation of biopsy proven disease
   AND
2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (such as azathioprine, cyclophosphamide, mycophenolate mofetil).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS):
1. Clinical documentation must be provided detailing patient’s primary symptom complex along with baseline clinical testing(s) using validated instrument(s)
   AND
2. A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient’s primary symptom complex. For example, treatments may include appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, or short-course antibiotic therapy). These trials may be done concurrently.

Reauthorization in PANDAS/PANS:
1. Documentation that a reevaluation at three months post treatment have been performed by an appropriate specialist
   AND
2. Documentation of objective clinically meaningful improvement posttreatment as defined by an improvement in the clinical testing with a validated instrument

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD)
1. Documentation of severe residual deficits following an initial attack, to prevent further disability (for example, to preserve vision in patients with residual monocular blindless after an initial attack)
   OR
2. As maintenance treatment for patients who have experienced at least one relapse following an initial attack

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

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

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

OTHER CRITERIA
N/A
INFUSION THERAPY SITE OF CARE

MEDICATION(S)
ACTEMRA 200 MG/10 ML VIAL, ACTEMRA 400 MG/20 ML VIAL, ACTEMRA 80 MG/4 ML VIAL, ADAKVEO, ALDURAZYME, ARALAST NP, ASCENIV, AVSOLA, BENLYSTA 120 MG VIAL, BENLYSTA 400 MG VIAL, CEREZYME, CRYSVITA, CUTAQUIG, CUVITRU, ELAPRASE, ELELYSO, ENTYVIO, FABRAZYME, FLEBOGAMMA DIF, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, GLASSIA, HIZENTRA, HYQVIA, INFLECTRA, INFLEXIMAB, KANUMA, LUMIZYME, MEPSEVII, NAGLAZYME, NEXVIAZYME, OCREVUS, OCTAGAM, ONPATTRO, ORENCIA 250 MG VIAL, PANZYGA, PRIVIGEN, PROLASTIN C, PROLIA, RADICAVA, REMICADE, RENFLEXIS, SIMPONI ARIA, SOLIRIS, TEPEZZA, ULTOMIRIS, VIMIZIM, VPRIV, VYEPTI, XEMBIFY, XGEVA, ZEMAIRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1. Prior authorization for the medication must be obtained, if necessary. Refer to individual drug specific policies for clinical criteria.
   a. For medications that require prior authorization for clinical criteria, the approval or denial of administration in an unapproved hospital outpatient setting is not indicative of approval or denial of the prior authorization for the medication based on clinical criteria.
2. The unapproved hospital-based outpatient infusion center may be considered medically necessary if one of the following criteria is met:
   a. The patient has concomitant conditions or clinical history that may increase the risk of infusion reactions or drug specific adverse events, defined as one of the following:
      i. Recent documented history of severe adverse drug reactions or anaphylaxis to prior treatments of the same or similar therapy.
      ii. Concomitant complex medical conditions that may increase the risk of infusion reactions or complications to therapy. For example, the presence of antibodies that may increase the risk of infusion reactions, severely compromised cardiac and respiratory function.
      iii. Use of multiple concurrent therapies of which one or more require infusion services at a higher level of care (e.g., cytotoxic chemotherapy, CAR-T given over same treatment period as requested medication)
      iv. Chronic vascular access complications that require hospital-based interventions or equipment not available to home infusion providers
   v. Mental health or cognitive changes that require increased level of care for the safe administration of
infusions

b. The unapproved hospital based infusion center is deemed a more appropriate option, as defined by BOTH of the following criteria:

i. An approved site of care would require an additional 15 miles of travel from the member’s home as compared to unapproved hospital based infusion center in the vicinity.

AND

ii. Home infusion services are not an option because the member’s home is ineligible for infusion services.

The eligibility of a member’s home for home infusion can be affected by such factors as:

1. The location of the member’s home being outside of the infusion provider’s service area, or
2. Upon inspection, the home infusion provider considers the member’s home to be unfit or unsafe for home infusion services.

3. The first 60 days after the drug authorization will be covered at an unapproved site of care, to accommodate for initial doses to be administered without delay to therapy. The purpose of the initial 60-day period is to allow for the determination of infusion tolerability at a higher level of care. This period will also allow for the timely submission and review of a prior authorization for the unapproved site of care, and the coordination of transition to an approved site, when the unapproved site of care has been determined to be not medically necessary.

4. An exception to the 60 days at an unapproved site will be granted for patients starting a new enzyme replacement medication. These drugs will be noted by an asterisk on table 1. Due to the prolonged concern with anaphylaxis reactions, an enzyme replacement drug that is new to the patient will be authorized for six months at an unapproved site of care.

AGE RESTRICTION
This policy applies to those members who are 13 years of age and older.

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA

Definitions:

1. Site of Care – the physical location where the infusion therapy is administered (e.g., an inpatient hospital, outpatient hospital-based infusion center, stand-alone infusion center, healthcare provider’s office, or home infusion)
2. Alternative Site of Care – any outpatient infusion site of care outside of an outpatient hospital-based infusion center (e.g., such as provider’s office or home infusion service providers
3. Approved Site of Care - alternative sites of care or approved hospital-based infusion centers
4. Unapproved Site of Care – any site of care that has been deemed as medically unnecessary, including unapproved hospital based infusion centers that increase the cost of care compared to approved sites of care
INJECTABLE ANTI-CANCER MEDICATIONS

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

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization:
1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For requests for trastuzumab or bevacizumab: Documented trial and failure, intolerance, or contraindication to the use of both preferred biosimilar medications, as follows:
   a. Trastuzumab preferred products: Ogivri® (trastuzumab-dkst) and Kanjinti® (trastuzumab-anns)
   b. Bevacizumab preferred products: Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb)

For patients established on therapy: 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

MEDICATION(S)
ARCALYST, ILARIS

COVERED USES
N/A

EXCLUSION CRITERIA
Combination therapy with another therapeutic immunomodulator (TIM) agent

REQUIRED MEDICAL INFORMATION
1. For all requests, the patient must have an FDA labeled indication for the requested agent or use to treat the indication is supported in drug compendia (such as the American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics’ DRUGDEX® System).
AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent
AND
3. One of the following:
a. For patients already established on the requested agent:
i. Documentation of positive response to therapy (e.g., improvement or stabilization of clinical symptoms of disease)
b. For patients not established on the requested agent, must meet ALL of the following criteria according to their diagnosis:
i. Cryopyrin-Associated Periodic Syndrome (CAPS) includes Familial Cold Autoinflammatory Syndrome (FCS) and Muckle-Wells Syndrome (MCS):
   • Diagnosis confirmed by laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3), also known as CIAS1 (Cold-Induced Autoinflammatory Syndrome-1)
   • Classic symptoms associated with CAPS (such as urticaria-like rash, fever, cold/stress-triggered episodes, sensorineural hearing loss, chronic aseptic meningitis, and skeletal abnormalities).
ii. Deficiency of Interleukin-1 Receptor Antagonist (DIRA):
   • Diagnosis confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist)
   • Classic symptoms associated with DIRA (such as pustular psoriasis-like rashes, osteomyelitis without bacterial infection, and nail changes)
   • Arcalyst® may be covered if:
o. Current inflammatory remission of DIRA
o. Weight of at least 10 kg
iii. Familial Mediterranean Fever (FMF):
• Diagnosis confirmed by laboratory evidence of genetic mutation in Mediterranean fever gene, MEFV
• Classic symptoms associated with FMF (such as febrile episodes, pain in the abdomen or chest, or arthritis of large joints)
• Documented trial and failure, contraindication, or intolerance to colchicine

iv. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD):
• Laboratory evidence of genetic mutation MVK (mevalonate kinase),
• Classic symptoms associated with HIDS (abdominal pain, lymphadenopathy, aphthous ulcers)

v. Recurrent Pericarditis (RP):
• Diagnosis of RP confirmed by an acute episode of pericarditis followed by a 4–6-week symptom free period prior to the next episode without an identified cause
• Documentation trial and failure, contraindication, or intolerance to NSAIDs or glucocorticoids

vi. Still’s Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still’s Disease (AOSD), must meet ONE of the following criteria:
• Documentation of trial and failure, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs) OR
• Presence of Macrophage Activation Syndrome

vii. Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS):
• Laboratory evidence of genetic mutation TNFRSF1A (Tumor Necrosis Factor Receptor Superfamily),
  AND
• Classic symptoms associated with TRAPS (such as long-lasting fever episodes, migratory rash, periorbital edema, and myalgia).

AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
KORSUVA

MEDICATION(S)
KORSUVA

COVERED USES
N/A

EXCLUSION CRITERIA
Use with peritoneal dialysis

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

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

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

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

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

**OTHER CRITERIA**

N/A
**MEDICATION(S)**
KRISTEXXA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For initial therapy, all the following criteria must be met:
1. Diagnosis of chronic gout
2. Documentation of inadequate response, intolerance or contraindication to both of the following at maximum medically appropriate doses:
   a. Xanthine oxidase inhibitor (such as allopurinol)
   b. Uricosuric agent (such as probenecid).
   Note: Inadequate response is defined as inability to achieve uric acid levels of less than 6 mg/dL after at least three months of continuous therapy.
3. Documentation of symptomatic gout, as defined by one or more of the following, despite therapies outlined in criterion 2 above:
   a. At least two gout flares per year
   b. Non-resolving tophi

Reauthorization requires documentation of a decreased uric acid level from baseline

**AGE RESTRICTION**
N/A

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

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
LEMTRADA

COVERED USES
N/A

EXCLUSION CRITERIA
In combination with other disease modifying therapy indicated for the treatment of multiple sclerosis

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria (1-4) must be met:
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease
2. Documentation of active disease (such as patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial (defined as at least six months of continuous therapy) of ocrelizumab (Ocrevus®)
3. Documentation of active disease after an adequate trial (defined as at least six months of continuous therapy) of at least one of the following additional disease modifying therapies unless all are contraindicated. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®) or interferon-beta 1b (Betaseron®)
   b. Generic dimethyl fumarate
   c. Glatiramer acetate (Copaxone®)
   d. Natalizumab (Tysabri®)
   e. Teriflunomide (Aubagio®)
   f. Fingolimod (Gilenya®)
   g. Ozanimod hydrochloride (Zeposia®)
   h. Siponimod (Mayzent®)
   i. Cladribine (Mavenclad®)
   j. Ofatumumab (Kesimpta®)
4. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy, all the following must be met:
1. Documentation of positive clinical response to therapy
2. Dose and frequency are in accordance with FDA-approved labeling

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist

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

OTHER CRITERIA
N/A
MEDICATION(S)
LUXTURNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
Approved for 12 months of age and older

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

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

OTHER CRITERIA
N/A
MEDICAL NUTRITION

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

COVERED USES
N/A

EXCLUSION CRITERIA
- L-methylfolate (such as Deplin®) in the treatment of depression
- Non- elemental enteral nutrition (such as Boost® and Ensure®) is considered a benefit exclusion when given orally based on plan limitations
- Use of oral thickening agent is considered a benefit exclusion based on plan limitations

REQUIRED MEDICAL INFORMATION
For coverage of oral or enteral nutrition, must meet the following criteria:

For Enteral Nutrition Via Feeding Tube
1. Member has a feeding tube and nutrition will be administered via feeding tube (e.g., nasogastric [NG], nasojejunal [NJ], gastrostomy [PEG], jejunostomy [J-tube, PEG-J, PEJ]
OR
2. ALL of the following:
   a. Established or anticipated inadequate oral intake for adults of at least seven days. For children and infants the length of time of inadequate oral intake will be considered on a case-by-case basis.
   AND
   b. Documentation of ONE of the following
      i. A medical condition that prevents food from reaching the digestive tract (for example, head and neck cancer with reconstructive surgery, central nervous system disease that interferes with neuromuscular mechanisms of ingestion).
      ii. Enteral nutrition comprises the sole source or is an essential source of nutrition (at least 75 percent of estimated basal caloric requirements) and is used as a therapeutic regimen to prevent serious disability in the patient.
      iii. Recent unplanned weight loss of at least 10% in the past three months or less due to: increased metabolic need resulting from severe trauma, malabsorption difficulties due to underlying medical condition/disease (for example, cystic fibrosis) or severe anorexia nervosa.
      iv. Documentation of failure to thrive in patients under the age of 17.
AND

c. Adequate nutrition is not possible by dietary adjustment and/or oral supplementation.

In-line cartridge containing digestive enzymes (such as Relizorb™)
ALL the following must be met:
1. Diagnosis of cystic fibrosis, AND
2. History of exocrine pancreatic insufficiency, AND
3. Member requires enteral tube nutrition for continuous durations of 6 hours or more

Elemental Formula
FOR INBORN ERRORS OF METABOLISM
ALL the following must be met:
1. Member has a confirmed in-born error of metabolism (including, but not limited to phenylketonuria [PKU], maternal phenylketonuria, maple syrup urine disease, citrullinemia, homocystinuria, histidinemia, tyrosinemia)
   AND
2. Failure to use medical food will predictably result in adverse medical outcomes
   AND
3. Treatment of the condition cannot be met through normal dietary supplementation or modification

Oral Administration
ALL the following must be met:
1. Member has a diagnosis of severe intestinal malabsorption (such as eosinophilic gastrointestinal disorder, severe Crohn’s disease, short bowel)
   AND
2. Documentation that enteral formula is the sole or essential source of nutrition (at least 75 percent of estimated basal caloric requirements), and is used as a therapeutic regimen to prevent serious disability in the patient
   AND
3. Treatment of the condition cannot be met through normal dietary supplementation or modification
   AND
4. A physician has issued a written order for the formula

For patients with milk allergy, nutrition supplementation may be covered if the following criteria are met:
1. Documentation that the allergy is severe and causing symptoms, such as eosinophilic esophagitis, food protein–induced enterocolitis syndrome, failure to thrive, or anaphylaxis reactions
   AND
2. Documentation that the requested nutritional support is the sole or essential source of nutrition (at least 75 percent of estimated basal caloric requirements)
   AND
3. Therapy has been recommended by a pediatric specialist and/or dietician

REAUTHORIZATION:
Continued coverage requires documentation that the requested therapeutic regimen is medically necessary to prevent serious disability in the patient

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for up to one year. For permanent or progressive conditions, authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA
N/A
MEDICALLY INFUSED THERAPEUTIC IMMUNOMODULATORS (TIMS)

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, ENTVYIO, ILUMYIA, INFLECTRA, INFIXIMAB, ORENCIA 250 MG VIAL, REMICADE, RENFLEXIS, SIMPONI ARIA, SKYRIZI 600 MG/10 ML VIAL, STELARA 130 MG/26 ML VIAL

COVERED USES
N/A

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

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

AND

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

AND

3. One of the following:
   a. For patients already established on the requested TIMs agent:
      i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
      ii. Requests for infliximab products Remicade® and Avsola® will require documentation of failure, intolerance, or contraindication to the preferred infliximab products Inflectra® AND Renflexis® in addition the indication-specific criteria below. Accepted contraindications include: contraindications listed in the package insert or a documented allergic reaction to an ingredient found only in the preferred biosimilar product(s).
      iii. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
   b. Patients not established on the requested TIMs agent must meet ALL of the following criteria:
      i. Requests for infliximab products Remicade® and Avsola® will require documentation of failure, intolerance, or contraindication to the preferred infliximab products Inflectra® AND Renflexis® in addition the indication-specific criteria below. Accepted contraindications include: contraindications listed in the package insert or a documented allergic reaction to an ingredient found only in the preferred biosimilar product(s).
      ii. For moderate to severe Ulcerative Colitis:
1. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®) or vedolizumab (Entyvio®)

iii. For moderate to severe Crohn’s Disease:
1. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®) or vedolizumab (Entyvio®)

iv. For Rheumatoid Arthritis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one oral disease modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

v. For moderate to severe Plaque Psoriasis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vi. For Psoriatic Arthritis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
2. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

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

viii. For giant cell arteritis:
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)

ix. For immune checkpoint inhibitor related diarrhea/colitis, a preferred infliximab product (Inflectra® or Renflexis®) may be covered if the following criteria are met:
1. Documentation of severe diarrhea/colitis (G3-4)
2. Documentation of inadequate response to a 1–2-day trial of intravenous prednisone or methylprednisolone

x. 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)

Note:
• Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent OR apremilast (Otezla®) for the same indication.
• Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical rationale
AGE RESTRICTION
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTION
• 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
• Systemic sclerosis-associated interstitial lung disease: must be prescribed by, or in consultation with, a pulmonologist or rheumatologist
• Giant cell arteritis: must be prescribed by, or in consultation with, a rheumatologist or neurologist
• Immune checkpoint inhibitor related diarrhea/colitis: must be prescribed by, or in consultation with, an oncologist or gastroenterologist

COVERAGE DURATION
• For immune checkpoint inhibitor related diarrhea/colitis: Authorization will be approved for three months
• For all other indications: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

OTHER CRITERIA
N/A
MEDICATIONS FOR RARE INDICATIONS

MEDICATION(S)
GAMIFANT, NULIBRY

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
Both of the following must be met:
1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted
   a. For Nulibry®: Diagnosis of molybdenum cofactor deficiency (MoCD) Type A confirmed by a mutation in
      the MOCS1 gene OR suspected molybdenum cofactor deficiency (MoCD) Type A
      AND
   2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy
      with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other
      clinical information
      AND
   3. For Pheburane Pellet (sodium phenylbutyrate): Documented trial and failure or intolerance to formulary
      generic sodium phenylbutyrate powder

REAUTHORIZATION CRITERIA:
The following must be met:
1. Documentation of successful response to therapy
   AND
2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy
   with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other
   clinical information
   AND
3. For Nulibry®: Genetic testing to confirm mutation in the MOCS1 gene (Nulibry® should be discontinued if
   the MoCD Type A diagnosis is not confirmed by genetic testing)

AGE RESTRICTION
N/A

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

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

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

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

**OTHER CRITERIA**
N/A
OPHTHALMIC VEGF INHIBITORS

MEDICATION(S)
BEOVU, CIMERLI, LUCENTIS, SUSVIMO, VABYSMO

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy with the requested medication (new start): Must have one of the following diagnoses and meet any required criteria:

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

2. Diabetic macular edema or Diabetic retinopathy:
   a. For faricimab (Vabysmo®) and brolucizumab (Beovu®):
      Documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
ii. aflibercept (Eylea®)
iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)

3. Macular edema following retinal vein occlusion:
   a. For ranibizumab (Lucentis®):
      Documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient:
      i. bevacizumab
      ii. aflibercept (Eylea®)
      iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)

4. Myopic Choroidal Neovascularization (mCNV):
   a. For ranibizumab (Lucentis®):
      Documentation that ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy with ranibizumab-nuna (Byooviz®) ranibizumab-eqrn (Cimerli®) is not appropriate for the patient

Reauthorization or continuation of therapy:
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
OSTEOANABOLIC AGENTS

MEDICATION(S)
EVENITY, EVENITY (2 SYRINGES)

COVERED USES
N/A

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

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

REQUIRED MEDICAL INFORMATION
For the treatment or prevention of osteoporosis
1. Must meet ONE of the following criteria (a-e):
   a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
   b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -3.0
   c. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 to -3.0 and high risk for fracture, defined as one of the following:
      i. Age more than 80 years
      ii. Chronic glucocorticoid use
      iii. Documented increased fall risk
   d. Patient has a spine or hip BMD T-score less than or equal to -2.5 to -3.0 and one of the following:
      i. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
      ii. Documented contraindication or intolerance to therapy with all the following: 1. denosumab, 2. oral bisphosphonate (such as alendronate), and 3. IV bisphosphonate therapy (such as zoledronic acid)
   e. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
      i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%
      ii. One of the following:
         1. Documented failure to anti-resorptive therapy (such as denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
         2. Documented contraindication or intolerance to therapy with all the following:
            a. Denosumab
            b. Oral bisphosphonate (such as alendronate)
            c. IV bisphosphonate therapy (such as zoledronic acid).
   2. For patients requesting teriparatide (Forteo®), brand or generic:
a. Documentation of trial and failure or intolerance to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos®.

AND

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

For authorization for teriparatide or brand Forteo® use exceeding two years in a lifetime, must meet both of the following criteria:
1. Documentation that previous treatment with teriparatide showed clinical improvement, defined as absence/decrease in frequency of new fragility fracture or stable/increased BMD T-score while on teriparatide
2. One of the following:
   a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide:
      i. BMD T-score continues to be less than or equal to -3.0
      ii. New vertebral or fragility fracture
   b. Documentation of worsening disease, defined as one of the following:
      i. A repeat BMD after discontinuation of therapy demonstrates a decline in BMD
      ii. New onset fragility fracture after discontinuation

AGE RESTRICTION
N/A

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

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

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

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

OTHER CRITERIA
N/A
OXLUMO

MEDICATION(S)
OXLUMO

COVERED USES
N/A

EXCLUSION CRITERIA
1. Patients with a history of liver transplant
2. Patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m²
3. Patients with secondary hyperoxaluria or genetic test positive for another form of primary hyperoxaluria such as type 2 and type 3 primary hyperoxaluria

REQUIRED MEDICAL INFORMATION
Initial authorization for new starts:
1. Patient has a diagnosis of primary hyperoxaluria type 1 (PH1)
2. Diagnosis of PH1 has been confirmed by one of the following:
   a. Genetic testing demonstrating mutation in the alanine: glyoxylate aminotransferase (AGXT) gene
   b. Liver biopsy demonstrating significantly decreased or absent alanine: glyoxylate aminotransferase (AGT) enzyme activity
3. Documentation of one of the following:
   a. Elevated urine oxalate (UOx) excretion as measured by body surface area-normalized daily UOx output greater than upper limit of normal (ULN)
   b. Elevated UOx excretion as measured by UOx: creatinine ratio above age-specific upper limit of normal (ULN) OR
   c. Elevated plasma oxalate (POx) concentration (POx concentration greater than ULN)
4. Documentation of a trial of high fluid intake of at least three liters per meter-squared of Body Surface Area (BSA) per day and that high fluid intake will continue with therapy
5. Concurrent use of pyridoxine or previous trial of at least three months with no significant improvement in urine oxalate concentration
6. Documentation of current patient weight and dosing not exceeding FDA-recommended dosing

Reauthorization or continuation of therapy:
1. Documentation of a clinically significant reduction in urine or plasma oxalate levels relative to pre-treatment baseline
2. Patient continues with concurrent high fluid intake (at least three liters per meter-squared BSA per day) and pyridoxine (unless individual is a pyridoxine non-responder)
3. Documentation of current patient weight and updated dosing not exceeding FDA-recommended dosing
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 six months. Reauthorization will be approved for 12 months.

OTHER CRITERIA
N/A
MEDICATION(S)
LEQVIO

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initial authorization
1. One of the following:
   a. Provider attestation of a trial and failure of at least eight weeks of therapy with a high-intensity statin therapy (specifically, atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering
   OR
   b. Provider attestation of statin intolerance, defined as one of the following:
      i. Rhabdomyolysis
      ii. Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation
      iii. Elevated liver enzymes
   OR
   c. The patient has an FDA labeled contraindication to a statin
2. Must meet listed criteria below for each specific diagnosis:
   a. For familial hypercholesterolemia (FH), one of the following must be met:
      i. A “possible” diagnosis of FH via Simon Broome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix)
      OR
      ii. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1
      OR
      iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns
   OR
iv. Presence of xanthomas

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

3. For Praluent® or Leqvio®:
   a. Documented trial and failure, intolerance, or contraindication to evolocumab (Repatha®)

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

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Initial authorization for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

**OTHER CRITERIA**
N/A
PITUITARY DISORDER THERAPIES

MEDICATION(S)
LANREOTIDE ACETATE, SANDOSTATIN LAR DEPOT, SIGNIFOR LAR, SOMATULINE DEPOT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy, must meet indication-specific criteria below:
1. For acromegaly, Signifor® LAR, Sandostatin® LAR, Somatuline® Depot, Somavert®, or Mycapssa® may be covered if all the following are met:
   a. Confirmed diagnosis of acromegaly
   b. Documentation that the patient has persistent disease (such as biochemical or clinical) following surgical resection or is not a candidate for surgical resection
   c. For coverage of Somavert® or Signifor® LAR, documentation of trial and failure, intolerance or contraindication to octreotide injection therapy or lanreotide subcutaneous depot
   d. For coverage of Mycapssa®, patient has been maintained (for at least six months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy

2. For Cushing’s syndrome (includes Cushing’s disease), Recorlev® may be covered if all the following are met:
   a. Diagnosis of endogenous Cushing’s syndrome (E24.9)
   b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery
   c. Documentation of baseline urinary free cortisol
   d. Documentation of baseline liver enzyme function tests
   e. Documentation of trial and failure of oral ketoconazole

3. For Cushing’s disease, Signifor®, Isturisa®, or Signifor® LAR may be covered if all the following are met:
   a. Diagnosis of endogenous Cushing’s disease (E24.0)
   b. Documentation the patient has failed pituitary surgery or is not a candidate for surgery

4. For carcinoid tumors or carcinoid syndromes, Sandostatin® LAR or Somatuline® Depot may be covered when there is documentation of severe diarrhea or flushing

5. For vasoactive intestinal peptide tumors, Sandostatin® LAR, Somatuline® Depot, may be covered when
there is documentation of severe diarrhea

6. For chemotherapy induced diarrhea, Sandostatin LAR® may be covered if all the following are met:
   a. Documentation that patient has severe diarrhea caused by chemotherapy
   b. Documentation of an inadequate response or contraindication to loperamide
   c. Documentation of good response and tolerability to short-acting octreotide

7. For AIDS-related diarrhea, Sandostatin LAR® may be covered if all the following are met:
   a. Documentation that patient has severe diarrhea
   b. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate/atropine (Lomotil®)
   c. Documentation of good response and tolerability to short-acting octreotide

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

For patients established on therapy, documentation of a positive clinical response must be provided. Appropriate documentation may include:
• For acromegaly, a reduction or normalization of IGF-1/GH level for same age and sex or reduction in tumor size
• For Cushing’s syndrome/Cushing’s disease, clinically meaningful reduction and maintenance in late-night salivary cortisol or 24-hour urinary free cortisol levels, or improvement in signs or symptoms of the disease
• For diarrhea, an improvement in the number of diarrhea episodes
• For carcinoid tumors or carcinoid syndromes, an improvement in the number of diarrhea and flushing episodes

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

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
PREVYMIS

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. All the following must be met for the prevention of cytomegalovirus (CMV) infection and disease:
   a. Member is within 100 days post-allogeneic transplant
   b. CMV Recipient positive
   c. If IV letermovir is being requested, rationale for not using oral formulation must be provided (such as patient is unable to swallow)

AGE RESTRICTION
May be approved for 18 years and older.

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

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

OTHER CRITERIA
N/A
PROPHYLACTIC HEREDITARY ANGIOEDEMA THERAPY

MEDICATION(S)
CINRYZE

COVERED USES
N/A

EXCLUSION CRITERIA
Combination prophylactic therapy with Cinryze®, Haegarda®, Takhzyro®, or Orladeyo®

REQUIRED MEDICAL INFORMATION
For initiation of therapy for prophylaxis of hereditary angioedema (HAE) attacks, all the following criteria (1-5) must be met:
1. Documentation of one of the following clinical criteria:
   a. Recurrent self-limiting, non-inflammatory subcutaneous angioedema without urticaria, or
   b. Recurrent, self-remitting abdominal pain without clear organic etiology, or
   c. Recurrent laryngeal edema
2. Documentation of at least two HAE attacks per month on average for the past three months despite removal of triggers (such as estrogen containing oral contraceptives, angiotensin converting enzyme inhibitors) unless medically necessary
3. One of the following:
   a. For HAE Type I and Type II, documentation of the following (per laboratory standard):
      i. C4 is below the lower limit of normal
      ii. One of the following:
         a. C1-inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or
         b. C1-INH function less than 50 percent of the lower limit of normal
   b. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII) ANGPT1, PLG, KNG1 gene mutation
      ii. Positive family history for HAE and attacks lack response to high dose antihistamines or corticosteroids.
4. Dose and frequency are in accordance with the Food and Drug Administration-approved labeling
5. For coverage of Cinryze®: Documentation of trial and failure, intolerance, or contraindication to Haegarda®.

For Patients Established on Therapy, all the following criteria (1-3) must be met:
1. Documentation of positive response to therapy, defined as reduction of frequency and severity of HAE attack episodes by at least 50% from baseline,
2. Dose and frequency are in accordance with the Food and Drug Administration-approved labeling,
3. For Takhzyro®: For patients established on Takhzyro® that are well-controlled (such as attack free) for
more than six months, the approved dose will be 300 mg every four weeks.

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
Initial prior authorization will be approved for six months. Reauthorization will be approved for one year.

**OTHER CRITERIA**
N/A
MEDICATION(S)
PROVENGE

COVERED USES
N/A

EXCLUSION CRITERIA
• Concomitant use of chemotherapy, systemic steroid medications at greater than physiologic replacement doses and/or other systemic immunosuppressive agents to treat autoimmune disease or prevent allogeneic transplant rejection
• Presence of hepatic or other visceral metastases

REQUIRED MEDICAL INFORMATION
All of the following criteria must be met:
1. Asymptomatic or minimally symptomatic metastatic disease (e.g. no opioid use for malignant cancer pain)
2. Castrate-resistant or castration-recurrent prostate cancer, defined as both of the following:
   a. Radiographic, clinical or biochemical [i.e., prostate-specific antigen (PSA)] progression despite therapy with androgen ablation therapy (e.g. orchiectomy, GnRH agonists/antagonists)
   AND
   b. Testosterone level less than 50 ng/dL
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
4. Life expectancy more than six (6) months

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist.

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 HYPERTENSION

MEDICATION(S)
EPOPROSTENOL SODIUM, FLOLAN, REMODULIN, REVATIO 10 MG/12.5 ML VIAL, SILDENAFIL 10 MG/12.5 ML VIAL, TREPENSTINIL, 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®)
• Idiopathic interstitial pneumonia for riociguat (Adempas®) only

REQUIRED MEDICAL INFORMATION
For brand Tracleer® tablets, Letairis®, or Opsumit®, must meet one of the following:
1. Patient has a documented allergy to an excipient found in all generic manufacturers’ products of bosentan and ambrisentan.
2. Patient has had a therapeutic failure to a generic formulation (bosentan OR ambrisentan). This is defined as the patient taking the medication as prescribed for an adequate duration and the therapeutic failure cannot be attributed to inadequate dosing.
3. Documented medical rationale for requiring use of Opsumit®, Tracleer® tablets, or Letairis® over generic bosentan or ambrisentan.
For Tracleer® tablets for suspension: Documented medical rationale for requiring use of a suspension over generically available tablets.

For patients initiating therapy, the following criteria must be documented:
1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization as defined by:
   i. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest
   AND
   ii. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg
   AND
   iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU)
   AND
2. Patient has one of the following:
   i. World Health Organization (WHO) Group 1 classification PAH with WHO/New York Heart Association (NYHA) functional class as outlined below:
      a. Flolan®, Veletri®, Tyvaso®, Tyvaso® DPI and Ventavis: Class III or IV
b. All other therapies: Class II, III, or IV
   ii. For Adempas® only, WHO Group 4 classification CTEPH with WHO/New York Heart Association (NYHA) functional class II, III, or IV
   iii. For Tyvaso®/Tyvaso® DPI only, WHO Group 3 classification PH-ILD

AND
3. For sildenafil citrate oral suspension or parenteral injection (Revatio®) and selexipag parenteral injection (Uptravi®): Documentation of intolerance or allergy to excipient ingredients of all available tablets or other medical rationale provided for use of oral suspension/parenteral injection over tablets.

For patients established on therapy, documentation of response to therapy such as lack of disease progression, improvement in WHO functional class must be provided.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or cardiologist

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

OTHER CRITERIA
N/A
MEDICATION(S)
RADICAVA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
N/A
REBLOZYL_MEDICAL BENEFIT

MEDICATION(S)
REBLOZYL

COVERED USES
N/A

EXCLUSION CRITERIA
1. Evidence of active pregnancy
2. History of thrombosis

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

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

For initial authorization for myelodysplastic syndrome (MDS), all of the following must be met:
1. Documentation of symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
2. Diagnosis of MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
3. Documentation of ring sideroblasts greater than or equal to 15% or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation
4. Documentation of a score of very low to intermediate risk based on the Revised International Prognostic Scoring System
5. Documentation that patient requires RBC transfusions of at least two units every eight weeks
6. One of the following:
a. Documented trial and failure [of at least two months], intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin) with or without a granulocyte-colony stimulating factor (such as filgrastim)
b. Documentation of endogenous erythropoietin level greater than 500 mU/mL

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

**AGE RESTRICTION**
At least 18 years of age

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

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

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
REBYOTA

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Authorization for the prevention of recurrence of Clostridioides difficile infection (CDI) requires all the following criteria be met:
1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode. Episodes must have occurred less than eight weeks after completion of treatment for a previous episode.
2. Positive stool test for C. difficile within 30 days before prior authorization request
3. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)

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

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

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

OTHER CRITERIA
N/A
RETHYMIC

MEDICATION(S)
RETHYMIC

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For authorization of a one-time implant, all the following must be met:
1. Diagnosis of congenital athymia confirmed by all the following criteria:
   a. Absence of genetic markers of severe combined immunodeficiency (SCID)
   b. Flow cytometry, defined as one of the following:
      i. Less than 50 naïve T cells/mm3 in the peripheral blood
      ii. Less than 5% of total T cells being naïve in phenotype
   c. One of the following:
      i. Genetic defect associated with congenital athymia [such as 22q11.2 deletion syndrome, forkhead box protein N1 (FOXN1) deficiency]
      ii. CHARGE syndrome
2. Documentation that infection control measures, including immunoprophylaxis, will be maintained until thymic function is established (immune reconstitution sufficient to protect from infection is unlikely to develop until 6-12 months after treatment)
3. Attestation from provider of absence of comorbidities, in the opinion of the treating clinician, that are reasonably likely to result in severe complications, including death, from administration of allogeneic processed thymus tissue
4. Dose will not exceed 42 slices

AGE RESTRICTION
N/A

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

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
RIABNI, RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For all requests for non-preferred rituximab products: Documented trial and failure, intolerance, or contraindication to the use of both preferred biosimilar medications: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs)

For initiation of therapy: Requests for rituximab may be approved for the following indications when the criteria below are met:
1. For Oncologic Diagnoses: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For Rheumatoid Arthritis:
   a. Documentation of trial, failure, intolerance, or contraindication to at least one of the following targeted immune modulators: etanercept (Enbrel®), adalimumab (Humira®), or a preferred infliximab product AND
   b. Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another disease-modifying antirheumatic drug (DMARD) (for example, leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.
3. For Vasculitis, including antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):
   a. Documentation that rituximab will be given in combination with glucocorticoids AND
   b. Documentation of severe disease (for example, critical organ system involvement)
4. For Immune Thrombocytopenia (ITP):
   a. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy AND
   b. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30,000 cells per microliter
5. For Relapsing and Remitting Multiple Sclerosis (RRMS): One of the following:
   a. Documentation of trial, failure, or intolerance to at least two disease modifying therapies indicated for RRMS
   OR
   b. Documentation that patient has highly active or aggressive disease

6. For Refractory Myasthenia Gravis:
   a. Documentation that patient has severely impaired function due to myasthenia gravis AND
   b. Documented trial, failure, intolerance, or contraindication to at least two of the following conventional therapies:
      i. Acetylcholinesterase inhibitors (for example, pyridostigmine)
      ii. Corticosteroids (for example, prednisone, methylprednisolone)
      iii. Immunosuppressive agents (for example, azathioprine, cyclosporine, mycophenolate)
      iv. Plasma exchange

7. For Autoimmune Hemolytic Anemia (AIHA):
   a. Diagnosis of warm AIHA and documentation of trial, failure, intolerance, or contraindication to glucocorticoids
   OR
   b. Diagnosis of cold AIHA or cold agglutinin disease

8. Confirmed diagnosis of Neuromyelitis Optica
9. Confirmed diagnosis of Moderate to Severe Pemphigus Vulgaris

For patients established on therapy: Documentation of adequate response to the medication must be provided.

AGE RESTRICTION
N/A

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

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

For non-oncologic diagnoses: Initial authorization will be approved for six months and reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
OTHER CRITERIA
N/A
MEDICATION(S)
RYPLAZIM

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initial authorization, all the following criteria must be met:
1. Diagnosis of plasminogen deficiency type 1 confirmed by one of the following:
   a. Genetic testing (biallelic pathogenic variants in PLG gene), or
   b. Confirmed hypoplasminogenemia (reduced plasminogen protein levels and functional activity)
2. Documentation of plasminogen activity level of 45% or lower of laboratory standard within the previous six months
3. Documentation of clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing)
For initial reauthorization, the following criteria must be met:
1. Documented positive response to therapy, defined as improvement in lesion number/size or improved function from baseline
For subsequent reauthorization, the following criteria must be met:
1. Documentation of no new or recurring lesions
2. Documentation that trough plasminogen activity levels are maintained at least 10% above baseline trough levels (indicating absence of anti-plasminogen antibodies)

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
**SAPNELO**

**MEDICATION(S)**
SAPNELO

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
Anifrolumab will not be approved if any of the following are present:
1. Severe active lupus nephritis
2. Severe active central nervous system lupus
3. Current use of other biologic immunomodulators
4. Concurrent use of voclosporin (Lupkynis®) or belimumab (Benlysta®)

**REQUIRED MEDICAL INFORMATION**
All of the following must be met:
Initial authorization:
1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist
   AND
2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following:
   a. Positive Antinuclear antibody (ANA)
   b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range
   c. Positive anti-Smith (Anti-Sm)
   d. Positive anti-Ro/SSA and anti-La/SSB antibodies
   AND
3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following:
   a. Oral corticosteroid(s)
   b. Azathioprine
   c. Methotrexate
   d. Mycophenolate mofetil
   e. Hydroxychloroquine
   f. Chloroquine
   g. Cyclophosphamide
   AND
4. Documentation that patient will continue to receive standard therapy (such as, corticosteroids,
hydroxychloroquine, mycophenolate, azathioprine, methotrexate)

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

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

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

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

OTHER CRITERIA
N/A
MEDICATION(S)
SCENESSE

COVERED USES
N/A

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

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

AGE RESTRICTION
Approved for 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a dermatologist or porphyria specialist
COVERAGE DURATION
Initial and reauthorization will be approved for six months for three implants (Medical justification is required for requests beyond three implants for seasonal coverage)

OTHER CRITERIA
N/A
SELF-ADMINISTERED DRUG (SAD) EXCLUSION

MEDICATION(S)
ARIXTRA, BETASERON, ENOXAPARIN SODIUM, EXTAVIA, FONDAPARINUX SODIUM, FRAGMIN, LOVENOX, NUCALA 100 MG/ML POWDER VIAL, RELISTOR 12 MG/0.6 ML SYRINGE, RELISTOR 12 MG/0.6 ML VIAL, RELISTOR 8 MG/0.4 ML SYRINGE, TEZSPIRE 210 MG/1.91 ML SYRINGE, XOLAIR 150 MG/ML SYRINGE, XOLAIR 75 MG/0.5 ML SYRINGE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Relevant chart notes are required and must document medical rationale for requiring administration by a healthcare professional.

Healthcare provider administration may be considered medically necessary if one of the following criteria is met:
1. History of anaphylaxis in the past five years, from any cause, that either required the use of epinephrine or resulted in hospitalization
2. History of allergic reaction to the requested medication
3. Documentation that the patient has one of the following that prevents self-administration:
   a. Mental health or cognitive changes that require increased level of care for the safe administration of medications
   b. Physical conditions or dexterity issues that impede clean handling of medication and safe administration technique
   c. Inability to recognize symptoms of anaphylaxis and/or act to treat anaphylaxis reactions appropriately
   d. Needle-phobia diagnosed by a mental health provider that is congruent with the most current DSM criteria for phobia. Please note that this does not include general fear of needles

AGE RESTRICTION
Refer to applicable clinical policy and/or formulary documents

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization and reauthorization for coverage under the medical benefit will be approved for one year
OTHER CRITERIA
N/A
SKYSONA

MEDICATION(S)
SKYSONA

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

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

AGE RESTRICTION
May be approved for patients aged 4-17 years

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

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

OTHER CRITERIA
N/A
SOLIRIS MEDICAL BENEFIT

MEDICATION(S)
SOLIRIS

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:
1. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (such as RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycophasmatidylinositol (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 (such as 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 (such as dysphagia or abdominal pain)
      v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
   AND
3. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
   AND
4. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for PNH:
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
For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
1. Diagnosis of non-infectious HUS, meaning 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. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
   AND
4. 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:
   a. Maintenance of platelet counts, meaning improvements or reductions less than 25%
   b. Reductions in LDH
   c. Reduction in number of needed plasmapheresis or plasma infusion events
   d. Improvement in kidney function and reduction of dialysis
2. Dose and frequency is in accordance with FDA-approved labeling

For Generalized Myasthenia Gravis (gMG), all of the following must be met:
1. Anti-acetylcholine receptor (anti-AChR) antibody positive
   AND
2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
   AND
3. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
   AND
4. Failed treatment for at least one year with the following:
   a. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids)
   OR
   b. ONE immunosuppressive therapy and required at least four infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)
   AND
5. Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris®)
   AND
6. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Myasthenia Gravis (MG):
1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from
baseline.
2. Dose and frequency is in accordance with FDA-approved labeling

For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following:
   a. 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
   b. Anti-AQP4 antibody positive
   AND
2. Documentation that other alternative diagnoses have been excluded, such as multiple sclerosis
   AND
3. Trial and failure, intolerance (such as neutropenia, LFT elevation, hypogammaglobulinemia) or contraindication to rituximab AND satralizumab (Enspryng®)
   AND
4. 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)
   AND
5. Dose and frequency is in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. 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)
3. 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
SPEVIGO

MEDICATION(S)
SPEVIGO

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
N/A

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

Requests for one additional dose may be approved one week after initial dose for treatment of the same flare if the following criteria are met:
1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher AND
2. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or higher
3. Dosing must be in accordance with FDA-approved labeling

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

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

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

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
SPINRAZA

COVERED USES
N/A

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

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

NOTE the following guidance on selecting an appropriate test:
• Non-sitters (infants and kids): CHOP-INTEND, HINE (may need HFSME as they transition to sitting).
• Sitters: HFSME, RULM
• Walkers (kids): 6WWT, HFSME
• Walkers (adults): 6MWT, RULM
• Non-walkers (adults): RULM

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

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a neurologist

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

OTHER CRITERIA
N/A
SPRAVATO

MEDICATION(S)
SPRAVATO

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of therapy, all the following criteria (1-4) must be met:
1. Confirmed diagnosis of one of the following:
   a. For treatment-resistant depression (TRD), clinical documentation must be provided that outlines the patient evaluation. TRD is defined as use of the following regimens (i and ii) for the current depressive episode:
      i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD).
      ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly).
   b. For MDD with acute suicidal ideation or behavior, documentation must be provided that patient has current suicidal ideation with intent defined as both of the following:
      i. Patient has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide, and
      ii. Patient intends to act on thoughts of killing themselves.
2. Baseline score from one of the following standardized depression rating scales confirming severe depression:
   a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20
b. Hamilton Depression Scale (HAMD17) score of at least 24

c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16

d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28

3. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy

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

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

1. Documentation of clinical improvement or sustained improvement from baseline in depression symptoms, documented by depression rating scores

2. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy

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

**AGE RESTRICTION**
Approved for 18 years and older

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

**COVERAGE DURATION**
Initial authorization will be approved for three months. Reauthorization will be approved for six months.

**OTHER CRITERIA**
N/A
SUNLENCA

MEDICATION(S)
SUNLENCA 463.5 MG/1.5 ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of therapy (new starts) all the following must be met:
1. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance, intolerance or contraindication to at least two (2) antiretroviral medications in each of at least three (3) following classes:
   a. Non-nucleoside reverse transcriptase inhibitor
   b. Nucleoside reverse transcriptase inhibitor
   c. Protease inhibitor
   d. Integrase strand-transfer inhibitor
2. Documentation current antiretroviral regimen has been stable for at least two months and current viral load is greater than or equal to 400 copies/mL
3. Confirmation that patient will take an optimized background regimen of antiretroviral therapy along with lenacapavir
4. Dose and frequency are in accordance with FDA-approved labeling

For patients established on therapy, all the following must be met:
1. Patient is currently receiving treatment with lenacapavir
2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy) of at least 0.5 log10 copies/mL. Note: A decrease in viral load less than 0.5 log10 copies/mL may be considered if there is documentation that a M66I mutation has not occurred
3. Confirmation that patient will continue to take an optimized background regimen of antiretroviral therapy
4. Dose and frequency are in accordance with FDA-approved labeling

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

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an infectious disease specialist
COVERAGE DURATION
Initial authorization will be approved for six (6) months.
Reauthorization will be approved for one year.

OTHER CRITERIA
N/A
**MEDICATION(S)**
SYFOVRE

**COVERED USES**
All Food and Drug Administration (FDA)-Approved Indications

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

**REQUIRED MEDICAL INFORMATION**
For initial authorization, all of the following criteria must be met:
1. Documentation of diagnosis of geographic atrophy (GA) confirmed by clinical exam or diagnostic imaging (such as Color Fundus Photography, Fundus Autofluorescence, Near Infrared Reflectance Imaging, Optical Coherence Tomography)
2. Documentation that GA is secondary to age-related macular degeneration (AMD)

For reauthorization, the following must be met: Documentation of response to therapy defined as one of the following:
1. Reduction in GA growth lesion
2. Documentation of improvement in visual function through visual function assessment test (such as normal luminance best-correct visual acuity [BCVA], maximum reading speed, Functional Reading Independence Index, microperimetry)

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

**PRESCRIBER RESTRICTION**
Must be prescribed by, or in consultation with, an ophthalmologist

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

**OTHER CRITERIA**
N/A
SYLVANT_MEDICAL BENEFIT

**MEDICATION(S)**
SYLVANT

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Initial Authorization:
1. Confirmed diagnosis of Multicentric Castleman Disease (MCD)
   AND
2. Documentation of negative human immunodeficiency virus (HIV) status
   AND
3. Documentation of negative human herpes-virus 8 (HHV-8) status
   AND
4. Documentation that siltuximab (Sylvant®) will be used as a single agent

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

**AGE RESTRICTION**
N/A

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

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

**OTHER CRITERIA**
N/A
T-CELL THERAPY

MEDICATION(S)
ABECMA, BREYANZI, CARVYKTI, KYMRIAHT, TECARTUS, TECVAYLI, YESCARTA

COVERED USES
N/A

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

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

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

AGE RESTRICTION
Abecma®: Approved for 18 years of age and older
Breyanzi®: Approved for 18 years of age and older
Carvykti®: Approved for 18 years of age and older
Kymriah®:
• Approved for 25 years of age or younger for acute lymphoblastic leukemia (ALL)
• Approved for 18 years of age and older for relapsed or refractory B-cell lymphomas
Tecartus®: Approved for 18 years of age and older
Yescarta®: Approved for 18 years of age and older

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

COVERAGE DURATION
For Tecvayli®: Initial authorization and reauthorization will be approved for one year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose.
For all other immunotherapies: Two months (limited to one treatment course per lifetime, with four doses of tocilizumab [Actemra®] at up to 800 mg per dose).

OTHER CRITERIA
N/A
MEDICATION(S)
TEPEZZA

COVERED USES
N/A

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

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

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

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
MEDICATION(S)
TEZSPIRE 210 MG/1.91 ML SYRING

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
1. For patients initiating therapy, all the following criteria must be met:
a. Documentation of treatment with maximally tolerated high-dose inhaled corticosteroid plus an inhaled long-acting beta-2 agonist and has been adherent to therapy in the past three months (this may be verified by pharmacy claims information),
b. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following
   i. Asthma Control Questionnaire (ACQ) score greater than equal to 1.5,
   ii. At least two asthma exacerbations require oral corticosteroids for at least three days in last 12 months,
   iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit
c. For patients with eosinophilic asthma or steroid-dependent asthma: Documented trial and failure, intolerance, or contraindication to therapy with dupilumab (Dupixent®)

AGE RESTRICTION
May be approved for patients aged 12 years and older

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

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

OTHER CRITERIA
N/A
THROMBOCYTOPENIA MEDICATIONS

MEDICATION(S)
NPLATE

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of therapy, must meet indication-specific criteria below:
1. For Oncologic Diagnoses: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

2. For Immune Thrombocytopenia (ITP), Doptelet®, Nplate®, Promacta®, or Tavalisse®, may be covered if all the following criteria (a-c) are met:
   a. Diagnosis of chronic immune thrombocytopenia (ITP)
   b. Platelet count of less than 30,000 cells per microliter
   c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated:
      i. Systemic corticosteroids
      ii. Immune globulin
      iii. Splenectomy
      iv. Rituximab
3. For Chronic Hepatitis C-associated Thrombocytopenia, Promacta® may be covered if all the following criteria (a-b) are met:
   a. Platelet count of less than 75,000 cells per microliter
   b. Patient will be initiating and maintaining interferon-based therapy or is currently receiving interferon-based therapy

4. For Severe Aplastic Anemia, Promacta® may be covered if there is documentation that the patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter

5. For Treatment of Thrombocytopenia in Patients with Chronic Liver Disease (CLD), all the following criteria (a-d) must be met:
   a. Request is for Doptelet® or Mulpleta®
i. For Mulpleta®: Documented trial, failure, intolerance, or contraindication to Doptelet®
b. Diagnosis of chronic liver disease
c. Platelet count of less than 50,000 cells per microliter,
d. Documentation that patient will have a scheduled medical or dental procedure within the next 30 days and therapy will be started prior to the procedure as follows:
   i. For Doptelet: 10-13 days prior to the procedure
   ii. For Mulpleta: 8-14 days prior to the procedure

6. For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], Nplate® may be covered if patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

For patients established on therapy, must meet indication-specific criteria below:
1. For oncologic diagnoses: Documentation of improved platelet levels from baseline

2. For ITP or severe aplastic anemia:
   a. Documentation of improved platelet levels from baseline
   b. Documentation the continued therapy is medically necessary to maintain a platelet count of at least 50,000 cells per microliter

3. For Chronic Hepatitis C-associated Thrombocytopenia:
   a. Documentation of improved platelet levels from baseline
   b. Patient continues to receive interferon-based therapy

4. For CLD or HSARS: Patient must meet the initial approval criteria above for each request

AGE RESTRICTION
N/A

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

COVERAGE DURATION
• For ITP, chronic hepatitis C-associated thrombocytopenia, severe aplastic anemia and oncologic diagnoses: Initial authorization will be approved for six months. Reauthorization will be approved for one year
• For CLD: Authorization will be approved for one month for one treatment course
• For HSARS: Authorization will be approved for three months

OTHER CRITERIA
TOTAL PARENTERAL NUTRITION (TPN)

MEDICATION(S)
AMINOSYN, AMINOSYN II, AMINOSYN II WITH ELECTROLYTES, AMINOSYN M, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E 2.75%-5% SOLUTION, CLINIMIX E 4.25%-10% SOLUTION, CLINIMIX E 5%-15% SOLUTION, CLINIMIX E 5%-20% SOLUTION, CLINIMIX E 8%-10% SOLUTION, CLINIMIX E 8%-14% SOLUTION, CLINISOL, CLINOLIPID, FREAMINE III, INTRALIPID 30% IV FAT EMUL, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, TRAVASOL, TROPHAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
Coverage for intradialytic parenteral nutrition (IDPN) when offered in addition to regularly scheduled TPN infusions

REQUIRED MEDICAL INFORMATION
One of the following criteria must be met:
1. Member has a central or peripheral line and nutrition will be administered via this line.
   OR
2. Documentation of a failure to enteral nutrition (either oral or via tube), defined as either a or b:
   a. A documented loss of at least 10% of body weight over a three-month period
   b. Member is unable to reach nutritional needs from combined oral and enteral intake (less than 75 percent of estimated basal caloric requirements)
   OR
3. Evidence of structural or functional bowel disease (e.g., massive small bowel resection, short bowel syndrome) that makes oral and tube feedings not possible
   OR
4. A condition in which it is necessary for the gastrointestinal tract to be totally non-functioning for a period of time (such as bowel rest)

Medically necessary intradialytic parenteral nutrition (IDPN) may be covered for members on chronic dialysis who meet criteria 2, 3 or 4 AND cannot tolerate daily TPN.

For continued coverage, annual assessment that documents the ongoing medical necessity of PN as per the above criteria will be required

AGE RESTRICTION
N/A
PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
N/A
TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
AMVUTTRA, ONPATTRO

COVERED USES
N/A

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

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

Reauthorization:
1. Documentation that patient is tolerating applicable therapy (vutrisiran (Amvutra®), inotersen (Tegsedi®))
or patisiran (Onpattro®))

AND

2. Documented improvement or stabilization in polyneuropathy symptoms from baseline, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) AND at least one of the following measures:
   a. Baseline polyneuropathy disability (PND) score
   b. Familial amyloid polyneuropathy (FAP) stage

AGE RESTRICTION
Approved for patients 18 years of age and older

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

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

OTHER CRITERIA
N/A
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 for Multiple Sclerosis, all of the following criteria (a-c) must be met:
   a. Must have one of the following confirmed diagnoses:
      i. Relapsing-remitting disease (RRMS)
      ii. Secondary progressive multiple sclerosis (SPMS)
      iii. Clinically isolated syndrome (CIS)
   b. One of the following:
      i. Documentation of trial, failure, or intolerance to at least one of the following disease modifying therapies:
         1. Interferon therapy (Avonex®, Rebif®, Plegridy®, or Betaseron®)
         2. Generic dimethyl fumarate
         3. glatiramer acetate (Copaxone®)
         4. teriflunomide (Aubagio®)
         5. fingolimod (Gilenya®)
         6. ocrelizumab (Ocrevus®)
         7. ozanimod hydrochloride (Zeposia®)
         8. siponimod (Mayzent®)
      OR
      ii. Documentation that patient has highly active or aggressive disease defined as one of the following:
         1. Relapse leading to deterioration in physical functioning or disabilities
         2. Magnetic resonance imaging (MRI) findings of new or worsening lesions
         3. Manifestations of multiple sclerosis-related cognitive impairment
   AND
   c. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
      i. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil
AND

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

2. For initiation of therapy for Crohn’s disease, all of the following criteria (a-c) must be met:
   a. Diagnosis of moderate to severe Crohn’s disease, AND
   b. Documentation of trial, failure, intolerance, or lack of response to a formulary TNF inhibitor (Remicade® and/or Humira®) indicated for Crohn’s, AND
   c. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
      i. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, and mycophenolate mofetil, AND
      ii. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

3. For patients established on therapy: Documentation of positive clinical response to therapy must be provided

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, 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
MEDICATION(S)
TZIELD

COVERED USES
All Food and Drug Administration (FDA)-Approved Indications

EXCLUSION CRITERIA
Stage 3 (symptomatic) type 1 diabetes

REQUIRED MEDICAL INFORMATION
Initial authorization requires all the following be met:
1. Diagnosis of stage 2 type 1 diabetes (meaning that the patient is at risk of developing symptomatic type 1 diabetes) as evidenced by both the following (a and b):
   a. Documentation of the presence of two or more of the following autoantibodies:
      • Glutamic acid decarboxylase 65 (GAD) autoantibody
      • Insulin autoantibody (IAA)
      • Insulinoma-associated antigen 2 autoantibody (IA-2A)
      • Zinc transporter 8 autoantibody (ZnT8A)
      • Islet cell autoantibody (ICA)
   b. Evidence of dysglycemia without overt hyperglycemia confirmed by an oral glucose tolerance test (meaning a 2-hour post prandial blood glucose of 140-199 mg/dL)
      Note: If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be considered such as fasting plasma glucose 100–125 mg/dL
2. Dosing is within FDA-labeled guidelines

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

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

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

OTHER CRITERIA
N/A
ULTOMIRIS_MEDICAL BENEFIT

MEDICATION(S)
ULTOMIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent therapy with Soliris® or Empaveli®

REQUIRED MEDICAL INFORMATION
For Paroxysmal Nocturnal Hemoglobinuria (PNH):
1. For initiation of therapy (new starts) all the following criteria (a-c) must be met:
   a. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64), and
   b. Severe disease as indicated by at least one of the following (i or ii):
      i. Documented history of thrombosis, OR
      ii. Documentation of at least 10% PNH type III red cells AND at least one of the following:
         1) Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
         2) Disabling fatigue
         3) End-organ complications
         4) Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
         5) Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal
   c. Dose and frequency is in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) or pegcetacoplan (Empaveli®) switching to ravulizumab (Ultomiris®) for PNH:
   a. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1a above) and severe disease (criteria 1b above). However, this can be based on patient’s history prior to starting eculizumab or pegcetacoplan.
   b. Dose and frequency are in accordance with FDA-approved labeling
3. For patients established on the requested agent for PNH, both of the following criteria must be met for continuation of therapy:
   a. Documentation of reduced LDH levels, reduced transfusion requirements, increase or stabilization of hemoglobin levels or improvement in PNH related symptoms
b. Dose and frequency are in accordance with FDA-approved labeling

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

For Generalized Myasthenia Gravis (gMG),
1. For initial authorization, all the following must be met:
   a. Anti-acetylcholine receptor (anti-AChR) antibody positive
   b. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
   c. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
   d. Failed treatment for at least one year with ONE of the following:
      i. At least TWO immunosuppressive therapies ([ISTs] such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids)
      ii. ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)
   e. Dose and frequency are in accordance with FDA-approved labeling
2. For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for gMG, both the following must be met:
   a. Confirmed documentation of gMG (criteria 1a-c above). However, this can be based on patient’s history prior to starting eculizumab.
   b. Dose and frequency are in accordance with FDA-approved labeling
3. Reauthorization for Myasthenia Gravis (MG):
   1. Initial reauthorization requires documentation of improvement in MG-ADL by at least two points from baseline.
   2. Dose and frequency are in accordance with FDA-approved labeling

**AGE RESTRICTION**
The patient’s age must be within FDA labeling for the requested indication

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

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

**OTHER CRITERIA**
N/A
**MEDICATION(S)**
UPLIZNA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
1. Diagnosis of neuromyelitis optica spectrum disorder as defined as both of the following:
   a. 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
   b. Anti-AQP4 antibody positive
2. Documentation that other alternative diagnoses have been excluded (such as Multiple Sclerosis)
3. For Commercial members: Trial and failure, intolerance, or contraindication to rituximab
4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
5. Dose and frequency are in accordance with FDA-approved labeling

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD):
1. Documentation of positive clinical response to therapy
2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies
3. Dose and frequency are in accordance with FDA-approved labeling

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

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

**COVERAGE DURATION**
Initial authorization will be approved for six months. Reauthorization will be approved for one year.
OTHER CRITERIA
N/A
**VYVGART_MEDICAL BENEFIT**

**MEDICATION(S)**
VYVGART

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

Reauthorization for Generalized Myasthenia Gravis (gMG), all the following must be met (1-2):

1. Documentation of improvement in MG-ADL by at least two points from baseline

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

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

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

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

**OTHER CRITERIA**
N/A
**XIAFLEX MEDICAL BENEFIT**

**MEDICATION(S)**
XIAFLEX

**COVERED USES**
N/A

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

**REQUIRED MEDICAL INFORMATION**

Initial Authorization Criteria:

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

For Peyronie’s disease (PD):
1. Patient’s disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound
3. Patient has intact erectile function, with or without the use of medications
4. Documentation of a functional impairment that is expected to improve with treatment (e.g., inability to have intercourse despite intact erectile function, due to curvature)
5. Documentation showing the patient does not have any of the following:
   a. Significant pain with palpation of the plaque
   b. Lack of full erectile response to prostaglandin E1 during curvature measurement
   c. Ventral curvature
   d. Calcified plaque
   e. Plaque located proximal to the base of the penis
6. Documentation that the patient has been counseled on expectations of treatment (e.g., expected average
curvature reduction is 17 degrees without reduction in pain or erectile dysfunction, potential for adverse effects)

Reauthorization Criteria:
For DC:
1. Documentation of fewer than three total injections in affected cord.

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

**AGE RESTRICTION**
Approved for 18 years and older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
For DC:
Initial authorization will be approved for three months for a maximum of three treatment courses. Reauthorization will be approved for three months, not to exceed three injections per affected cord.

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

**OTHER CRITERIA**
N/A
MEDICATION(S)
XOLAIR

COVERED USES
N/A

EXCLUSION CRITERIA
Concurrent use with anti-IL5 (such as mepolizumab, reslizumab, benralizumab), anti-IgE, anti-TSLP (such as tezepelumab), or anti-IL4 (such as dupilumab) monoclonal antibodies

REQUIRED MEDICAL INFORMATION
For asthma, must meet all of the following criteria:
1. Diagnosis of moderate to severe persistent allergic asthma
2. IgE baseline levels greater than 30 IU/ml
3. Positive skin test to a common perennial aeroallergens
4. 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)
5. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
b. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months
c. At least one exacerbation requiring hospitalization
Reauthorization for asthma requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

A. Asthma
1. For patients initiating therapy, all the following criteria must be met:
a. Diagnosis of moderate to severe persistent allergic asthma
b. IgE baseline levels greater than 30 IU/ml
c. Positive skin test to a common perennial aeroallergens
d. Documentation that, in the past three months, patient is adherent to treatment with maximally tolerated doses of both of the following, taken concurrently, unless patient has an intolerance to an inhaled steroid and a LABA, LTRA, or LAMA or has a contraindication to ALL therapies (This may be verified by pharmacy claims information):
i. Inhaled corticosteroid
ii. One of the following:
1) A long-acting inhaled beta 2-agonist (LABA)
2) A leukotriene receptor antagonist (LTRA)
3) A long-acting muscarinic antagonist (LAMA)
e. Documentation of inadequate asthma control despite above therapy, defined as one of the following:
i. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
ii. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months
iii. At least one exacerbation requiring hospitalization, emergency room or urgent care visit in the last 12 months
iv. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
v. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted

2. For patients established on therapy for asthma: Documentation of response to therapy indicating improvement or stabilization of condition

B. Chronic Spontaneous (Idiopathic) Urticaria
1. For initial authorization, one of the following criteria (a or b) must be met:
a. All of the following criteria must be met:
i. Patient has had over 6 weeks of hives and itching
ii. Documentation that the condition is idiopathic and that secondary causes of urticaria (such as offending allergens, physical contact, etc.) have been ruled out
iii. Trial and failure of a second-generation non-sedating H1 antihistamine (such as levocetirizine, loratadine, cetirizine, fexofenadine)
iv. Trial and failure of one additional medication from one of the following classes: leukotriene receptor antagonists (such as montelukast), first generation H1 antihistamine (such as diphenhydramine), or histamine H2-receptor antagonist (such as famotidine, ranitidine)

2. For reauthorization for chronic spontaneous urticaria: Documentation of response to therapy indicating improvement or stabilization of condition

C. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. For initial authorization, all of the following criteria must be met:
a. Evidence of bilateral nasal polyposis by direct examination, endoscopy or sinus CT scan
b. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (such as fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
c. Documentation that patient will continue standard maintenance therapy (such as intranasal corticosteroids, nasal saline irrigation) in combination with omalizumab

2. For reauthorization for CRWsNP: Documentation of response to therapy indicating improvement or stabilization of condition
AGE RESTRICTION

- Asthma: May be approved for patients six years of age or older
- Urticaria: May be approved for patients 12 years of age or older
- Chronic rhinosinusitis with nasal polyps: May be approved for patients 18 years of age or older

PRESCRIBER RESTRICTION

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

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

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

COVERAGE DURATION

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

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

Chronic rhinosinusitis with nasal polyps: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

OTHER CRITERIA

N/A
**ZINPLAVA_MEDICAL BENEFIT**

**MEDICATION(S)**
ZINPLAVA

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

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

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

**AGE RESTRICTION**
Approved for 18 years of age and older

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

**COVERAGE DURATION**
Initial authorization and reauthorization will be approved for a one-time intravenous
OTHER CRITERIA
N/A
ZOLGENSMA_MEDICAL_BENEFIT

MEDICATION(S)
ZOLGENSMA

COVERED USES
N/A

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

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

AGE RESTRICTION
May be covered for patients two years of age and under

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

COVERAGE DURATION
Authorization will be approved for a one-time infusion

OTHER CRITERIA
N/A
**MEDICATION(S)**
ZYNTEGLO

**COVERED USES**
All Food and Drug Administration (FDA)-Approved Indications

**EXCLUSION CRITERIA**
N/A

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

**AGE RESTRICTION**
May be approved for patients aged four years and older

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

**COVERAGE DURATION**
Authorization will be limited to one treatment course per lifetime

**OTHER CRITERIA**
N/A