MEDICATION(S)
ADAKVEO

COVERED USES
N/A

EXCLUSION CRITERIA
Used in combination with voxelotor

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 6 months
   b. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least 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 (1) of the following:
   a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 uM/L (approximately 57 mg/dL by nephelometry or 80mg/dL by immunodiffusion)
   b. Patient has one of the high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null), or PI*SZ homozygotes

2. Diagnosis of emphysema confirmed by one (1) of the following:
   a. Forced expiratory volume per one second (FEV1) of 35 to 65% of predicted volume
   b. Rapid lung function decline as evidence by reduction of FEV1 of 100 mL/year or greater

3. Documentation that the patient has never smoked or has abstained from smoking for at least the previous 6 months required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

QUANTITY LIMIT:
60 mg/kg infused every 7 days, subject to audit.
Note: Dose may be rounded down to the nearest gram (0.5 gm for Aralast®) within 10% of calculated dose.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization for 6 months. Reauthorization for one year.
OTHER CRITERIA
N/A
MEDICATION(S)
ARANESP, EPOGEN, PROCRIT, RETACRIT

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with uncontrolled hypertension
Anemia induced from hepatitis C therapy

REQUIRED MEDICAL INFORMATION
Hemoglobin and Hematocrit levels within 30 days prior to initiation of therapy.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be for one (1) year

OTHER CRITERIA
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 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
   b. Treatment of anemia in patients with cancer:
      i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level 100 mcg/L or serum transferrin saturation 20%
AND

ii. One of the following clinical scenarios:
1. Patient has comorbid chronic kidney disease
2. Patient undergoing palliative treatment
3. Patient is currently on myelosuppressive chemotherapy and anemia is not able to be managed by transfusion therapy

b. Treatment of Anemia in Myelodysplastic Syndromes (MDS) or with myelofibrosis
   i. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level 100 mcg/L or serum transferrin saturation 20%
   ii. Must have documented current (within last 3 months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL

c. Anemia associated with zidovudine-treated HIV-infection patients
   i. Documented current (within last 3 months) endogenous serum erythropoietin level is less than or equal to 500 mU/ml
   ii. Zidovudine dose is less than or equal to 4200 mg/week

d. 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 (e.g., expected to lose more than 2 units of blood)
   iii. Patient is unwilling to donate autologous blood pre-operatively

Reauthorization:
1. Documentation of continued medical necessity (e.g., ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days
MEDICATION(S)
BENLYSTA

COVERED USES
N/A

EXCLUSION CRITERIA
Belimumab will not be approved if any of the following are present:
1. Severe active lupus nephritis (presence of proteinuria of greater than or equal to 3.5 gm/day)
2. Severe active central nervous system lupus
3. Current use of other biologic immunomodulator
4. Current use of intravenous (IV) cyclophosphamide

REQUIRED MEDICAL INFORMATION
• ANA, anti-dsDNA antibody, or anti-Sm antibody
• For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary
• For IV infusion only: patient’s weight

AGE RESTRICTION
Age 5 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

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

OTHER CRITERIA
All of the following must be met:
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 (1) of the following:
   a. Positive Antinuclear antibody (ANA)
b. Positive anti-double-stranded DNA (anti-dsDNA) on two (2) 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 (1) of the following:

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

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

Reauthorization:

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

2. Patient currently receiving standard therapy for SLE (excluding IV cyclophosphamide)

QUANTITY LIMIT:

- Belimumab 200 mg/mL single-dose prefilled autoinjector and glass syringe for subcutaneous injection: 4 mL per 28 days
- Belimumab powder for solution for IV use only (subject to audit): Initial dose of 10 mg/kg IV every 2 weeks for 3 doses and then continue every 4 weeks thereafter as maintenance
- Belimumab IV is available as:
  o 120 mg in a 5-mL single-dose vial
  o 400 mg in a 20-mL single-dose vial for injection
- Correct vial combination for each patient should be calculated to minimize waste (see Appendix 1)
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
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
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 4 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 (3) 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. Documentation that onabotulinumtoxinA will not be used in combination with Calcitonin Gene-Related
Peptide (CGRP) Inhibitors (e.g., Aimovig®)
2. Upper and lower limb spasticity in adults
3. Upper limb spasticity in pediatric patients at least 2 years of age
4. Lower limb spasticity in pediatric patients at least 2 years of age that is not due to cerebral palsy
5. Cervical dystonia in adults
6. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
7. 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.
8. 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)
9. Urinary incontinence in adults:
   a. Due to detrusor overactivity 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)
10. Excessive salivation due to advanced Parkinson’s disease
11. Hemifacial spasm

AbobotulinumtoxinA (Dysport®) may be covered for the following indications:
1. Spasticity in adults
2. Cervical dystonia in adults
3. Lower-limb spasticity in patients at least 2 years of age
4. Upper limb spasticity in pediatric patients at least 2 years of age that is not due to cerebral palsy.
5. Blepharospasm in adults

IncobotulinumtoxinA (Xeomin®) may be covered for the following indications:
1. Chronic sialorrhea in adult patients
2. Upper limb spasticity in adult patients
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
BRINEURA - MEDICAL BENEFIT

MEDICATION(S)
BRINEURA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tests to confirm a diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) as required for “other criteria”, baseline CLN2 disease clinical rating scale score.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
May be covered for ages 3-17 years

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

COVERAGE DURATION
Initial approval and reauthorization will be for 1 year

OTHER CRITERIA
Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) with all of the following:
1. Deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity, in the setting of normal activity of a control enzyme such as palmitoyl-protein thioesterase 1 (PPT1) and/or ?-galactosidase (a sample of leukocytes, dried blood spot, fibroblasts, or saliva may be used): AND
2. Genetic testing revealing one pathogenic mutation on each parental allele of TPP1/CLN2: AND
3. Documentation of symptomatic disease (seizures, changes in gait, falls, difficulty in ambulating, loss of language/delay in language development, visual failures): AND
4. Baseline Motor Domain of the CLN2 Clinical Rating Scale score of at least 1 (Appendix 1)

Reauthorization requires documentation of response to therapy, as defined as:
1) No more than a 1-point decline in the Motor Domain of the CLN2 Clinical Rating Scale: AND
2) Motor Domain of the CLN2 Clinical Rating Scale score remains above 0.
MEDICATION(S)
PROBUPHINE, SUBLOCADE

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of chronic pain

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

For Sublocade®: Initial authorization and reauthorization will be approved for 6 months

OTHER CRITERIA
For Probuphine®:
Initial Authorization:
1. Documentation of opioid use disorder
2. Patient has been clinically stable for at least 3 months on 8 mg per day or less of a transmucosal buprenorphine product (i.e. Subutex® or Suboxone® sublingual tablet or generic equivalent). (The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine®)
3. Medical rational of why patient cannot be continued on maintenance therapy with a transmucosal buprenorphine product.
4. Documentation that Probuphine® will be used along with counseling and/or psychosocial support
Reauthorization:
1. Documentation that patient has experienced treatment success (i.e. abstinence from other opioids)
2. Documentation that Probuphine® will be continue to be used along with counseling and/or psychosocial support
3. Documentation that this is the second course of therapy to be inserted into the contralateral arm. (Treatment beyond 2 courses has not been studied in clinical trials and is not considered medically necessary).

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

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

QUANTITY LIMIT:
For Propuphine®: 1 kit (4 implants) per 6 months, lifetime limit of 1 insertion in each arm (2 kits)
For Sublocade®: 1 injection per 28 days
MEDICATION(S)
CABLIVI

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION
Initial authorization will be approved for 30 days. Reauthorization will be approved up to a total duration of 58 days post-plasma-exchange.

OTHER CRITERIA
Initial Criteria:
1. Diagnosis of acquired thrombotic thrombocytopenic purpura
2. Documentation that therapy will be given in combination with plasma exchange therapy
3. Documentation that therapy will be given in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab)

Reauthorization criteria:
If the request is for a new treatment cycle:
1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab)
3. Documentation that length of therapy post plasma exchange will not exceed 58 days
4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange. If request is for treatment extension:

1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency
3. Documentation that length of therapy post plasma exchange will not exceed 58 days

QUANTITY LIMIT:
1 vial per day
CALCITONIN GENE-RELATED PEPTIDE RECEPTOR (CGRP) ANTAGONISTS FOR MIGRAINE PROPHYLAXIS

MEDICATION(S)
AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK), AJOVY AUTOINJECTOR, AJOVY SYRINGE, EMGALITY PEN, EMGALITY SYRINGE, VYEPTI

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For chronic (not episodic) migraine prophylaxis and cluster headaches: Must be prescribed by, or in consultation with, a headache specialist [e.g., neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties (UCNS)]

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
Initial authorization for migraine prophylaxis (chronic and episodic):
1. Diagnosis of migraine headaches with at least four (4) headache days per month
   AND
2. One of the following:
a. Trial and inadequate response to at least 6 weeks of at least one (1) prophylactic medication from one (1) of the following categories:
   i. Anticonvulsants (i.e., divalproex, valproate, topiramate)
   ii. Beta-blockers (i.e., metoprolol, propranolol, timolol)
iii. Antidepressants (i.e., amitriptyline, venlafaxine)
b. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above
AND
3. Documentation that if the patient is currently receiving botulinum toxin, treatment with botulinum toxin will be discontinued.
4. The patient has been evaluated for, and does not have, medication overuse headache
5. For non-preferred CGRP prophylactic agents (Ajovy®, Vyepti®): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig® and Emgality®)

Initial authorization for cluster headaches (Emgality® only):
1. Diagnosis of episodic cluster headaches with all of the following:
a. A history of at least five (5) cluster headache attacks with at least two of the cluster periods lasting at least 7 days
b. Cluster periods are separated by at least three (3) months of pain-free remission
AND
2. One of the following:
a. Trial and inadequate response to at least 6 weeks (while adherent to therapy) of at least one (1) of the following:
i. Verapamil
ii. Melatonin
iii. Lithium
iv. Topiramate
b. Documented intolerance or contraindication to all of the therapies listed above
AND
3. The patient has been evaluated for, and does not have, medication overuse headache

Reauthorization for all indications: Documented reduction in the severity or frequency of headaches.
CAR-T (KYMRIAH, YESCARTA) - MEDICAL BENEFIT

MEDICATION(S)
KYMRIAH, YESCARTA

COVERED USES
N/A

EXCLUSION CRITERIA
• Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy
  o Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established
• History of allogenic stem cell transplantation and primary central nervous system (CNS) lymphoma
• Presence of history of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, brain metastases, or any autoimmune disease with CNS involvement
• Active infection or inflammatory disorder (including hepatitis B or C, human immunodeficiency virus [HIV], active graft vs. host disease)

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes (e.g., original pathology report, treating oncologist chart notes) documenting medical rationale are required.

AGE RESTRICTION
Kymriah:
• 25 years of age or younger for acute lymphoblastic leukemia (ALL)
• 18 years of age and older for relapsed or refractory large B-cell lymphoma
Yescarta:
• 18 years of age and older

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

COVERAGE DURATION
2 months (limited to one treatment course per lifetime, with 4 doses of tocilizumab [Actemra®] at up to 800mg per dose).

OTHER CRITERIA
For all indications, the following criteria must be met:
• Documentation of adequate bone marrow, cardiac, pulmonary and organ function (e.g., kidney) to
minimize risks of serious adverse reactions (e.g., cytokine release syndrome)

For B-cell precursor acute lymphoblastic leukemia (ALL), Kymriah may be approved when all of the following criteria are met:
1. Documentation of cluster of differentiation 19 (CD19) positive, B-cell precursor acute lymphoblastic leukemia (ALL): and
2. Disease is considered refractory, or in second or later relapse, as defined by any one of the following scenarios:
   a. Second or later bone marrow relapse: or
   b. Bone marrow relapse after allogenic stem cell transplant: or
   c. Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy): or
   d. Chemorefractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease): and
3. Member is not eligible for allogenic stem cell transplant: and
4. For Philadelphia chromosome (Ph)-positive disease only: Have failed adequate trials of, contraindication, or intolerance to two (2) prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib)
5. Performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance score is 0-3

Note: For patients aged 18 years and younger with minimal residual disease (MRD) after consolidation therapy, NCCN guidelines have given category 2B recommendation for use as a single-agent therapy.

For relapsed or refractory large B-cell lymphoma, Yescarta or Kymriah may be approved when all of the following criteria are met:
1. Confirmed diagnosis of relapsed or refractory FDA approved large B-cell lymphomas (see FDA Approved Indications below/package insert)
2. Refractory or relapse to two (2) or more prior treatment regimens (e.g. TKI): and
   a. For Follicular Lymphoma: Previous therapy must have included an anthracycline (e.g. doxorubicin) or anthracenedione-based regimen, unless contraindicated or if therapy was previously not tolerated
   b. For CD20+ disease: Previous therapy must have included an anti-CD20 monoclonal antibody (e.g. rituximab), unless contraindicated or if therapy was previously not tolerated
3. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
4. Member is not eligible for allogenic stem cell transplant
MEDICATION(S)
CINRYZE, HAEGARDA, TAKHZYRO

COVERED USES
N/A

EXCLUSION CRITERIA
Combination prophylaxis therapy with Cinryze®, Haegarda®, or Takhzyro®

REQUIRED MEDICAL INFORMATION
Complement Component C4 and C1-Esterase inhibitor OR C1-Esterase Functional.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
Current patient weight

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 3 months. Reauthorization may be approved for one year.

OTHER CRITERIA
All of the following must be met:
1. Documentation of one of the following clinical criteria:
a. Self-limiting, noninflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
c. Recurrent laryngeal edema
AND
2. Documentation of greater than or equal to 2 HAE attacks per month on average for the past 3 months despite removal of triggers (eg. estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary
AND
3. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone unless not indicated (eg. pregnancy, lactation, pre-pubescent children), AND

4. One of the following:
   a. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show:
      i. C4 is less than 50 percent of the lower limit of normal AND
      ii. one of the following:
         a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
         b. C1-INH function is less than 50 percent of the lower limit of normal
   b. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII) mutation OR
      ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

For coverage of Cinryze®: Documentation of trial and failure or contraindication to Haegarda®.

REAUTHORIZATION: Documentation must be provided showing benefit of therapy with reduction of frequency and severity of HAE attack episodes by greater than or equal to 50% from baseline.

QUANTITY LIMITS:
Cinryze®: 16 vials (500 units each vial) for 28 days
Haegarda®: Weight based 60 units/kg twice weekly for a 28-day supply (see appendix 2)
Takhzyro®: 2 vials (300 mg each vial) per 28-day supply

Dosing regimens beyond quantity limits will only be approved if evidence-based-rationale is provided.
CRYSVITA - MEDICAL BENEFIT

MEDICATION(S)
CRYSVITA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale, patient’s weight and serum phosphorus levels are required, and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary as well as patient’s weight and serum phosphorus levels.

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 6 months and reauthorization will be approved for 1 year.

OTHER CRITERIA
Initial authorization:
1. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following:
   a. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance
   b. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 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
MEDICATION(S)
DUPIXENT SYRINGE

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

Eosinophilic and corticosteroid dependent asthma: Absolute Eosinophil Count, and Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ) score

AGE RESTRICTION
• Moderate-to-severe atopic dermatitis: Age 12 years and older
• Eosinophilic and corticosteroid dependent asthma: Age 12 years and older
• Chronic rhinosinusitis with nasal polyposis: Age 18 years and older

PRESCRIBER RESTRICTION
• Moderate-to-severe atopic dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist
• Eosinophilic and corticosteroid dependent asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)
• Chronic rhinosinusitis with nasal polyposis: otolaryngologist, allergist, pulmonologist

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

OTHER CRITERIA
For initial authorization, must meet all of the following criteria:

For moderate-severe atopic dermatitis:
1) Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following:
a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot or mucous membrane involvement)
b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification
c. Chronic condition, affecting patient for more than one (1) year
d. For Medicaid (OHP) only: Documentation that patient is having functional impairment due to atopic dermatitis (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)

2) Documented trial and failure of an adequate treatment course with at least one agent from all each of the following treatment modalities:
a. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two (2) weeks
b. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least one (1) month
c. For Medicaid only: Systemic immunomodulatory agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate or oral corticosteroids) for at least two (2) months unless contraindicated

Reauthorization requires documentation of reduction from baseline of flares, pruritus, and affected BSA

For eosinophilic asthma:
1. Documentation of eosinophilic asthma by one of the following:
a. A blood eosinophil count greater than 150 cells/microliter in the past 12 months
b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high –dose inhaled corticosteroid plus a long-acting inhaled β2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with 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 1.5
b. At least 2 asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
c. At least 1 asthma exacerbation requiring hospitalization, emergency room or urgent care visit

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

For corticosteroid dependent asthma:
1. Documentation of corticosteroid dependent asthma defined as consistent treatment with oral corticosteroids for the past six months (5 mg to 35 mg of prednisone/prednisolone (or equivalent)). (This may be verified by pharmacy claims information).
2. Documentation that in the past 3 months patient is adherent to a combination of a high-dose inhaled corticosteroid and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)

3. Documentation of severe asthma with 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 1.5
   b. Documentation, within the last 12 months, of one or more asthma exacerbations defined as any of the following:
      i. Increase in dose of systemic corticosteroid treatment
      ii. Urgent care visit or hospital admission
      iii. Intubation

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following must be met:
1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan
2. Documentation of one (1) of the following:
   a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery
   b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
3. Patient has tried and had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids
4. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with dupilumab

Reauthorization for CRSwNP: Documentation of positive clinical response to therapy such as symptom improvement

QUANTITY LIMIT:
Two (2) 200 mg injections per 28 days
Two (2) 300 mg injections per 28 days.

Note:
• The recommended dose of Dupixent® for adults with atopic dermatitis is an initial loading dose of 600 mg (two 300 mg injections) subcutaneously, followed by 300 mg given every other week for maintenance.
• The recommended dose of Dupixent® for adolescents (12 year of age and older) for eosinophilic and oral corticosteroid dependent asthma is an initial loading dose of 400 mg (two 200 mg injections) or 600 mg (two 300 mg injections) subcutaneously, followed by 200 mg or 300 mg given every other week for maintenance.
• The recommended dose of Dupixent® for adults with CRSwNP is 300 mg every other week
EGRIFTA

MEDICATION(S)
EGRIFTA, EGRIFTA SV

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Waist circumference

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA
1. Patient must be at least 18 years old and have a diagnosis of HIV-associated lipodystrophy AND
2. Documentation of patient’s waist circumference
   a. Waist circumference greater than or equal to 37.4 inches (95 cm) for males
   b. Waist circumference greater than or equal to 37 inches (94 cm) for females
   AND
3. Documentation of waist-to-hip ratio
   a. Waist-to-hip ratio greater than or equal to 0.94 for males
   b. Waist-to-hip ratio greater than or equal to 0.88 for females
   AND
4. Documentation of a body mass index (BMI) greater than 20 kg/m2
   AND
5. Documentation of fasting blood glucose (FBG) of less than or equal to 150 mg/dL (8.33 mmol/L) AND
6. Documentation that patient has been on a stable regimen of antiretrovirals for at least 8 weeks

Reauthorization will require documentation of clinical improvement (e.g., decrease in waist circumference, improvement in visceral adipose tissue).
ELZONRIS

MEDICATION(S)
ELZONRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial and reauthorization will be approved for 6 months

OTHER CRITERIA
For initial authorization all of the following criteria must be met:
1. Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN)
2. Documentation that patient has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1
3. Documentation that patient has a baseline serum albumin level of at least 3.2 g/dL
4. Documentation that patient has adequate cardiac function, defined as LVEF of at least 50% and none of the following:
   a. Uncontrolled or any NYHA Class 3 or 4 congestive heart failure
   b. Uncontrolled angina
   c. History of myocardial infarction or stroke within 6 months of initiating therapy
   d. Uncontrolled hypertension
   e. Clinically significant arrhythmias not controlled by medication
Reauthorization requires documentation of positive response to therapy, such as a lack of disease progression
ENZYME REPLACEMENT THERAPY

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

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization and any dose increases will require a current (within 6 months) patient weight. For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
• Aldurazyme®: N/A
• Cerezyme®: N/A
• Elaprase®: The safety and efficacy of Elaprase® have not been established in pediatric patients less than 16 months of age
• Elelyso®: The safety and efficacy of Elelyso™ have not been established in pediatric patients less than 4 years of age
• Fabrazyme®: Safety and efficacy not established in pediatric patients under 8 years of age
• Kanuma®: N/A
• Lumizyme®: N/A
• Mepsevii®: N/A
• Naglazyme®: N/A
• Vimizim®: The safety and effectiveness of Vimizim® have not been established in pediatric patients less than 5 years of age
• Vpriv®: The safety and efficacy of Vpriv® have not been established in pediatric patients less than 4 years of age

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

COVERAGE DURATION
Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.

OTHER CRITERIA
Documentation of FDA-labeled indication (Appendix) for the following products:
• Aldurazyme® (laronidase)
• Cerezyme® (imiglucerase)
• Elaprase® (idursulfase)
• Elelyso® (taliglucerase alfa)
• Fabrazyme® (agalsidase beta)
• Kanuma® (sebelipase alfa)
• Lumizyme® (alglucosidase alfa)
• Mepsevii® (vestronidase alfa-vjbk)
• Naglazyme® (galsulfase)
• Vimizim® (elosulfase alfa)
• Vpriv® (velaglucerase alfa)

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

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

**MEDICATION(S)**
EVENITY, EVENITY (2 SYRINGES)

**COVERED USES**
N/A

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

**REQUIRED MEDICAL INFORMATION**
For treatment or prevention of osteoporosis: BMD T-score, FRAX
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

**AGE RESTRICTION**
N/A

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

**COVERAGE DURATION**
May be approved for up to 1 year, ensuring the total duration of Evenity® therapy does not exceed 1 year of total therapy duration.

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

MEDICATION(S)
EXONDYS-51, 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
Eteplirsen (Exondys® 51) and golodirsen (Vyondys® 53) are not considered medically necessary and will not be covered, at this time, due to the lack of clinical evidence of improved outcomes and safety.
EXTAVIA

MEDICATION(S)
EXTAVIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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
Documentation of trial and failure, contraindication, or intolerance to two of the following OR medical rationale why therapies cannot be tried:

a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
b. Interferon-beta 1b (Betaseron®)
c. Dimethyl fumarate (Tecfidera®)
d. Glatiramer acetate (Copaxone®)
e. Teriflunomide (Aubagio®)
f. Fingolimod (Gilenya®)
MEDICATION(S)
FORTEO, TERIPARATIDE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BMD T-score, FRAX.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
May be approved for up to 2 years, ensuring the cumulative duration of osteoanabolic therapy does not exceed 2 years in a lifetime. Duration of osteoanabolic therapy is defined as cumulative duration spent on any of the three therapies: abaloparatide, teriparatide, or romosozumab.

OTHER CRITERIA
For the treatment or prevention of osteoporosis
1. Must meet ONE of the following criteria:
   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 -2.5 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
   c. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following:
      i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
ii. Documented contraindication or intolerance to therapy with all of the following: 1. denosumab, 2. oral bisphosphonate (e.g., alendronate), and 3. IV bisphosphonate therapy (i.e., zoledronic acid)
d. 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 (e.g., 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 of the following:
         a. Denosumab
         b. Oral bisphosphonate (e.g., alendronate)
         c. IV bisphosphonate therapy (i.e., zoledronic acid)
   2. For female patients only:
      a. Documentation of trial and failure to Tymlos® (abaloparatide). Failure is defined as a new fracture or worsening bone mineral density while adherent to Tymlos® (abaloparatide).
      AND
      b. Total duration of treatment with Tymlos® (abaloparatide) has not exceeded two years.
GAMIFANT

MEDICATION(S)
GAMIFANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient’s weight
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization approved for 3 months: reauthorization for 1 month

OTHER CRITERIA
Initiation Criteria:
1. Diagnosis of primary HLH based on a molecular diagnosis OR family history consistent with primary HLH OR 5 out of the following 8 criteria fulfilled:
   a. Fever
   b. Splenomegaly
   c. Cytopenias affecting 2 of 3 lineages in the peripheral blood: hemoglobin less than 9 g/dL, platelets less than 100 x 109/L, neutrophils less than 1 x 109/L
   d. Hypertriglyceridemia (fasting triglycerides greater than 3 mmol/L or equal or greater than 265 mg/dL) and/or hypofibrinogenemia (equal or less than 1.5 g/L)
   e. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
   f. Low or absent NK-cell activity
   g. Ferritin equal or greater than 500 mcg/L
   h. Soluble CD 25 equal or greater than 2400 U/mL
2. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (corticosteroids, methotrexate, cyclosporine A, etoposide, anti-thymocyte globulin) based on one of the following criteria:
   a. Having not responded or not achieved a satisfactory response
   b. Having not maintained a satisfactory response to conventional HLH therapy
   c. Intolerance to conventional HLH treatments
3. Patient is a candidate for stem cell transplant and emapalumab is being used as part of the induction or maintenance phase for stem cell transplant and will be discontinued at the initiation of conditioning for stem cell transplant
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling
5. Documentation that patient currently has no active infection (e.g. mycobacteria and Histoplasma Capsulatum)

Reauthorization Criteria:
1. Patient continues to be a candidate for stem cell transplant
2. Documentation of disease improvement such as:
   a. Complete response defined as normalization of all HLH abnormalities (i.e. no fever, no splenomegaly, neutrophils greater than 1x10⁹/L, platelets greater than 100x10⁹/L, ferritin less than 2,000 µg/L, fibrinogen greater than 1.50g/L, D-dimer less than 500 µg/L, normal CNS symptoms, no worsening of sCD25 greater than 2-fold baseline)
   b. Partial response defined as normalization of ≥3 HLH abnormalities
   c. HLH improvement defined as ≥3 HLH abnormalities improved by at least 50% from baseline
3. Documentation that patient is being monitored for serious infections (such as tuberculosis, adenovirus, EBV, and CMV)
4. Documentation that dose does not exceed max FDA approved dosing of 10 mg/kg per dose for two doses per week
MEDICATION(S)
ASCENIV, BIVIGAM, CARIMUNE NF NANOFILTERED, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMASTAN, GAMASTAN S-D, GAMMAGARD LIQUID, GAMMAGARD S-D 10 G (IGA<1) SOL, GAMMAGARD S-D 5 G (IGA<1) SOLN, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient weight, dose, frequency and duration

IgA, IgM, IgG, T4 cell count, anti-GM1, platelet counts may be required (See indication specific criteria)

For initiation, a prior authorization form and documentation of medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by or in consultation with an appropriate specialist (i.e. a Neurologist for Multiple Sclerosis or an immunologist, hematologist or infections disease expert for Primary Immunodeficiency)

COVERAGE DURATION
Generally, initial authorization is up to 6 months subject to criteria and reauthorization is up to 1-year subject to criteria. See Table 2 for indication specific coverage duration

OTHER CRITERIA
Initial Authorization for ALL indications:
1. The medical diagnosis a 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 (See Table 1). 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 case basis. Dosing is subject to audit.

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

Indication-Specific Requirements:

Primary immune deficiency disorders such as agammaglobulinemia, hypogammaglobulinemia (i.e., common variable immunodeficiency), Hyper-IgM (i.e., X-linked or autosomal recessive hypogammaglobulinemia), Wiskott-Aldrich syndrome or Secondary immunodeficiency due to drugs/biologics agents, underlying disease or other causes:
1. Documentation of significant recurrent infections
AND
2. One of the following:
   a. Laboratory evidence of immunoglobulin deficiency:
      i. Agammaglobulinemia (total pre-treatment IgG less than 200 mg/dL)
      ii. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dl, or at least two standard deviations below normal, on at least two occasions)
   OR
   b. Deficiency in producing antibodies in response to vaccination

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 500 mg/dL
AND
2. History of recurrent, severe bacterial infections (e.g., pneumonia, sinusitis, otitis media)

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

Idiopathic or Immune Thrombocytopenic Purpura (ITP):
(Platelet counts expressed per mm3 and should be obtained within the past 30 days)

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

Pregnant Women with ITP:
1. Documentation of one of the following:
   a. Platelet count is less than 100,000
   b. Past history of splenectomy
   c. Past history of delivered infant with autoimmune thrombocytopenia

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

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

Reauthorization: Documented response to therapy

Chronic inflammatory demyelinating polyneuropathy (CIDP):
1. Documentation of severe disability
   AND
2. One of the following:
   a. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. prednisone or methylprednisolone)
   b. Documentation of pure motor CIDP
Autoimmune Hemolytic Anemia:
1. Documented trial, failure, intolerance or contraindication to systemic corticosteroids (i.e. prednisone or methylprednisolone)
   AND
2. Documented trial, failure, intolerance or contraindication to another conventional therapy for autoimmune hemolytic anemia (e.g., splenectomy, cyclophosphamide, azathioprine, cyclosporine)

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

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

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

Myasthenia Gravis:

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

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

Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients:
1. Therapy is requested for use within 100 days after transplantation (documentation of transplantation date must be documented)
OR
2. Documentation of that member has hypogammaglobulinemia (see criteria for Secondary Hypogammaglobulinemia)

Autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis
1. Documentation of biopsy proven disease
AND
2. Documented trial, failure, intolerance or contraindication to systemic corticosteroids with concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).
GONADOTROPIN RELEASING HORMONE AGONISTS

MEDICATION(S)
ELIGARD, LEUPROLIDE 2WK 1 MG/0.2 ML KIT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LUPANETA PACK, LUPRON DEPOT, LUPRON DEPOT-PED, SUPPRELIN LA, SYNAREL, TRIPTODUR, VANTAS, ZOLADEX

COVERED USES
N/A

EXCLUSION CRITERIA
Treatment of male infertility.

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Anemia from fibroids: Authorization will be approved for up to 3 months (NO reauthorization)
Uterine leiomyomata (fibroids): Authorization will be approved for 4 months. No reauthorization
Endometriosis: For Lupron® and Lupaneta® Pack – authorization/reauthorization will be approved for up to 6 months (total of 12 months): For Synarel®/Zoladex® - initial authorization for up to 6 months and no reauthorization
CPP: Authorization/reauthorization will be approved for up to one year
GID: Authorization/reauthorization will be approved for up to one year
Endometrial Thinning/Dysfunctional Uterine Bleeding: Initial authorization for 2 months. No reauthorization.
Oncological Indications: Authorization/reauthorization will be approved for one year
In vitro fertilization: Authorization/reauthorization will be approved for one year

OTHER CRITERIA
For oncological indications: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
For anemia associated with uterine leiomyomata (fibroids)
1. Documented trial, failure, intolerance or contraindication to at least 30 days of therapy with iron supplementation alone
   AND
2. Documentation that Lupron® will be used in combination with iron supplementation

For uterine leiomyomata (fibroids)
1. Documentation that surgical removal of fibroids is planned within 4 months
   AND
2. And one of the following, less invasive surgical methods will be employed:
   a. Documentation of an enlarged uterus that will require a midline rather than transverse incision.
   b. Documentation that shrinking the uterus or fibroids will allow for a vaginal hysterectomy rather than an abdominal procedure.

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

Reauthorization for Lupron® requires documentation that it will be used in combination with “add-back” progesterone therapy (e.g. norethindrone) to help prevent bone mineral density loss.
Reauthorization for Synarel® and Zoladex® is not recommended. Treatment is only recommended for up to 6 months with these agents for endometriosis

For central precocious puberty
Note, a one-time dose may be approved for diagnostic purposes
For Initial Authorization:
1. Documentation of a history of early onset of secondary sexual characteristics (age 8 years and under for females or 9 years and under for males)
   AND
2. Confirmation of diagnosis by one (1) of the following:
   a. Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [e.g., stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)]
   b. Pubertal level of basal LH levels (0.3 IU/L or greater)
   c. Bone age advanced one year beyond the chronological age
   AND
3. For Synarel®: documented trial and failure or contraindication/intolerance to Lupron® and, either Triptodur® or Supprelin LA®
For Reauthorization:
1. Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level), and
2. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression.

Discontinuation of leuprolide should be considered before age 11 years for females and age 12 years for males. However, treatment discontinued at the appropriate age of onset of puberty should be at discretion of the treating provider.

For Gender Identity Disorder (GID):
1. Documented diagnosis of Gender Identity Disorder (GID) by a qualified mental health professional
2. Prescribed by or in consultation with an endocrinology specialist
3. Demonstration that puberty has progressed to a minimum of Tanner Stage 2 by:
   a. Documentation of estrogen and testosterone levels
   OR
   b. Other sufficient evidence provided

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

MEDICATION(S)
HEMLIBRA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Initial authorization and reauthorization will require a current weight (within the past 6 months). For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization: 6 months
Reauthorization: 12 months

OTHER CRITERIA
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 ≥ 5 Bethesda units per milliliter)
   b. Severe hemophilia (defined as pre-treatment factor VIII level less than 1%)
   c. Moderate hemophilia (defined as pre-treatment factor VIII level of 1% to less than 5%) or mild hemophilia (defined as pre-treatment factor VIII level of 5% to less than 40%) with:
      i. One (1) or more spontaneous episodes of bleeding into the central nervous system, large joints (ankles, knees, hips, elbows, shoulders) or other serious, life-threatening bleed

When the above criteria are met, Hemlibra® (emicizumab-kxwh) will be approved for a loading dose of 3 mg/kg once weekly for 4 weeks, followed by any of the three (3) maintenance dosing regimens below:
• 1.5 mg/kg once weekly
• 3 mg/kg every 2 weeks
• 6 mg/kg every 4 weeks

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

MEDICATION(S)
BERINERT, FIRAZYR, ICATIBANT, KALBITOR, RUCONEST

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Required laboratory tests: Complement Component C4 and C1-Esterase inhibitor OR C1-Esterase Functional
Current patient weight

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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 6 months. Reauthorization will be approved for up to 1 year.

OTHER CRITERIA
All of the following must be met:
1. Diagnosis of Hereditary Angioedema Types (HAE) I, II or III and one of the following clinical criteria:
a. Self-limiting, non-inflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
b. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
c. Recurrent laryngeal edema.
AND
2. One of the following:
   A. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show:
      i. C4 is less than 50 percent of the lower limit of normal
      AND
      ii. one of the following:
         a. C1-Inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
         b. C1-INH function is less than 50 percent of the lower limit of normal
   B. For HAE with normal C1-INH or HAE Type III:
      i. Confirmed Factor 12 (FXII) mutation
      OR
      ii. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

For quantities exceeding the formulary quantity limit:
1. Documentation of frequent HAE attacks defined as greater than or equal to 2 attacks per month on average.
   AND
2. Trial and failure, intolerance or contraindication to long-term prophylaxis with androgen therapy, such as danazol, stanozolol or oxandrolone.

QUANTITY LIMIT (subject to audit):
Berinert® - 2 injections per 30 days
Ruconest® - 2 injections per 30 days
Kalbitor® - 2 boxes (6 vials) per 30 days
Firazyr® - 3 injections (3 boxes, total of 9ml) per 30 days
MEDICATION(S)
ACTHAR, H.P. ACTHAR

COVERED USES
N/A

EXCLUSION CRITERIA
All other indications beside infantile spasms are not considered medically necessary and are excluded for coverage.

REQUIRED MEDICAL INFORMATION
Body Surface Area
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization/reauthorization will be approved for one month.

OTHER CRITERIA
For infantile spasm: H.P. Acthar Gel® will be approved for one month of therapy at the following dose: 75 units/m2 injected intramuscularly twice daily

Reauthorization will require medical rationale for continuing treatment, as recommended treatment duration is for 2 weeks followed by two-week taper to avoid adrenal insufficiency.
MEDICATION(S)
CINQAIR, FASENRA, FASENRA PEN, NUCALA

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initial authorization, must meet all of the following criteria:

For eosinophilic asthma:
1. Documentation of eosinophilic asthma by one of the following:
   a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months
   b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids
2. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus a long-acting inhaled beta2-agonist and has been compliant to therapy in the past 3 months (this may be verified by pharmacy claims information)
3. Documentation of severe asthma with 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 (2) asthma exacerbations requiring oral systemic corticosteroids in the last 12 months
   c. At least one (1) asthma exacerbation requiring hospitalization, emergency room or urgent care visit

For Eosinophilic Granulomatosis with Polyangiitis (EGPA):
1. Request is for Nucala®
2. History or presence of asthma
3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
4. At least two of the following clinical findings:
   a. Biopsy evidence of eosinophilic vasculitis
   b. Motor deficit or nerve conduction abnormality
   c. Pulmonary infiltrates
   d. Sinonasal abnormality
   e. Cardiomyopathy
   f. Glomerulonephritis
   g. Alveolar hemorrhage
h. Palpable purpura
i. Positive test for ANCA

5. Documentation of one of the following
a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous 2 years while receiving at least 7.5 mg/day prednisone (or equivalent)

OR

b. Failure to achieve remission following a standard induction regimen administered for at least 3 months OR recurrence of symptoms of EGPA while tapering of glucocorticoids

i. 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

Reauthorization documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

QUANTITY LIMIT:
Nucala® syringe and auto injector: 1 per 28 days (quantities of 3 per 28 days are approvable for EGPA)
Fasenra® Pen: 1 per 56 days (quantities of 1 per 28 days will be allowed for 3 month for initial loading dose)

AGE RESTRICTION
Nucala®: Approved for 6 years of age or older
Cinqair®: Approved for 18 years of age or older
Fasenra®: Approved for 12 years of age or older

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

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

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

OTHER CRITERIA
N/A
INCRELEX

MEDICATION(S)
INCRELEX

COVERED USES
N/A

EXCLUSION CRITERIA
Subjects with secondary forms of Insulin-like growth factor (IGF)-1 deficiency:
• GH deficiency
• Malnutrition
• Hypothyroidism
• Chronic treatment with pharmacologic doses of anti-inflammatory steroids
Concurrent use of growth hormone therapy
Malignant neoplasia

REQUIRED MEDICAL INFORMATION
Plasma IGF-1 activity, blood glucose, plasma insulin, connecting peptide (C-peptide), glycosylated hemoglobin, serum electrolytes, liver enzymes.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For Severe primary IGF-1 deficiency:
1. Height standard deviation score of less than or equal to -3.0
   AND
2. Basal insulin-like growth factor (IGF)-1 standard deviation score of less than or equal to -3.0
   AND
3. Normal or elevated growth hormone (GH) levels.
AND
4. Documentation of open epiphyses by bone radiograph

For Growth hormone (GH) gene deletion
1. Documentation of open epiphyses by bone radiograph
AND
2. Patient has developed neutralizing antibodies to growth hormone

Reauthorization will require evidence that the medication remains effective, growth velocity is above 2.0 cm/year, evidence of open epiphyses, and documentation of expected adult height goal that is not yet obtained.
INFERTILITY AND RELATED HORMONE MEDICATIONS

MEDICATION(S)
CHORIONIC GONAD 10,000 UNIT VL, CHORIONIC GONAD 12,000 UNIT VL, CHORIONIC GONAD 6,000 UNIT VL, CRINONE, ENDOMETRIN, FOLLISTIM AQ, GANIRELIX ACETATE, GONAL-F, GONAL-F RFF, GONAL-F RFF REDI-JECT, MENOPUR, NOVAREL, OVIDREL, PREGNYL, PROCHIEVE

COVERED USES
N/A

EXCLUSION CRITERIA
The treatment of infertility is a benefit exclusion for the Oregon Health Plan

Medications used in all forms and variations for Assisted Reproductive Technology (ART) are excluded from coverage, except for those groups with the benefit covering ART [including in vitro fertilization (IVF)].

REQUIRED MEDICAL INFORMATION
I. For treatment of infertility (subject to benefit limitations) must meet criteria for specific cause of infertility as follows:
   1. For females with anovulation due to hypothalamic-pituitary failure, gonadotropins may be covered if the following criteria is met:
      i. Low pre-treatment level of serum estradiol concentrations
      AND
      ii. Low or low-normal serum follicle-stimulating hormone (FSH) or luteinizing hormone (LH) levels
      AND
      iii. Normal body mass index achieved (defined as BMI greater than 18.5) if anovulation is documented to be caused by low body weight
   2. For females with anovulation associated with polycystic ovarian syndrome (PCOS), gonadotropins may be covered if one (1) of the following criteria is met:
      i. Documented failure, contraindication or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles)
      OR
      ii. Documented failure, contraindication or intolerance to letrozole (failure defined as failure to conceive after at least three cycles)
   3. For hyperprolactinemia in females or males, gonadotropins may be covered if the all the following criteria are met:
      i. Documented failure, contraindication, or intolerance to dopamine agonists (e.g., bromocriptine or cabergoline)
      AND
ii. For females, documented failure, contraindication, or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles)

4. For females with Primary Ovarian Insufficiency (POI) or diminished ovarian reserve, gonadotropins may be covered as part of assisted reproductive technology (ART), subject to IVF benefit, if the following criteria is met:
   i. Both low pre-treatment serum estradiol levels AND elevated follicle stimulating hormone (FSH) levels OR
   ii. Low antral follicle count (AFC), based on specific laboratory reference range (usual cutoff is less than 6)

5. For females with anatomical abnormalities related to the fallopian tube, uterus (i.e. endometriosis, intrauterine adhesions), or cervix or couples with unexplained infertility, gonadotropins may be covered if one (1) of the following criteria is met:
   i. Documented failure, contraindication or intolerance to clomiphene (failure defined as failure to conceive after at least three cycles)
   OR
   ii. Documented failure, contraindication or intolerance to letrozole (failure defined as failure to conceive after at least three cycles)
   OR
   iii. Documentation of irreversible cause for infertility (i.e. bilateral tubal obstruction, inoperable uterine abnormality, endometriosis)

6. For male factor infertility, requests for gonadotropins may be covered if the following criteria is met:
   i. Documentation of low sperm production or sperm defects
   OR
   ii. Documentation of anatomical abnormality or obstruction, congenital or developmental disorder, or acquired disorder of the testes

II. For maintenance of pregnancy, progesterone formulations may be approved if the following criteria is met:
   1. Documentation of current pregnancy
   OR
   2. Documentation that patient has history of prior pregnancy loss

III. For males with cryptorchidism, human chorionic gonadotropin (hCG) therapy may be approved if the following criteria is met:
   1. Patient is between the ages of 4 and 9 years
      AND
   2. Documentation that cryptorchidism is not due to anatomic obstruction

AGE RESTRICTION
Female must be less than 45 years of age for treatment of infertility unless being used for ART.
PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, a gynecologist, urologist, or endocrinologist.

COVERAGE DURATION
Authorization will be approved for one year

OTHER CRITERIA
N/A
INFUSION THERAPY SITE OF CARE

MEDICATION(S)
ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE, INFLECTRA, OCREVUS, ORENCIA, ORENCIA CLICKJECT, REMICADE, RENFLEXIS

COVERED USES
N/A

EXCLUSION CRITERIA
Certain commercial plan members (Providence Saint Joseph Health employer group)

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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 (1) year

OTHER CRITERIA
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, which may include, but are not limited to:
      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, documentation of severe immunosuppression and/or the presence of antibodies that may increase the risk of infusion reactions.

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

v. Mental health or cognitive changes that require increased level of care for the safe administration of infusions

vi. Age of member is less than 13 years of age.

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

i. The approved sites 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. If criterion 2a or 2b is not met, infusions occurring during the first 60 days of the authorization period may be covered in an unapproved hospital-based infusion center or higher level of care than the approved site of care to allow time for assessment and coordination of an infusion at an approved site of care.

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 centers (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, ACTIMMUNE, ADCETRIS, ALIQOPA, ALKERAN 50 MG VIAL, ARRANON, ARZERRA, ASPARLAS, AVASTIN, AZACITIDINE, AZEDRA DOSIMETRIC, AZEDRA THERAPEUTIC, BAVENCIO, BELEODAQ, BELRAPZO, BENDAMUSTINE HCL, BENEKA, BESPONS, BLINCYTO, BORTEZOMIB, CYRAMZA, DACOGEN, DARZALEX, DECITABINE, EMPILICITI, ENHERTU, ERBITUX, FASLODEX, FOLOTYN, FULVESTRANT, HALAVEN, HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, IMFINZI, IMLYGIC, ISTODAX, IXEMPRA, JEVTANA, KADCYLA, KANJINTI, KEYTRUDA, KYPRELLIS, LARTRUVO, LIBTAYO, LUMOXITI, LUTATHERA, MELPHALAN HCL, MVASI, OGIVRI, ONIVIDE, ONTRUZANT, OPDIVO, PADCEV, PERJETA, POLIVY, PORTRAZZA, POTOLOGEO, ROMEDEPSIN, SARCLISA, SYLATRON, SYLATRON 4-PACK, SYNBRIO, TECENTRIQ, TEMODAR 100 MG VIAL, TEMSIROLIMUS, TORISEL, TRAZIMERA, TREANDA, VECTIBIX, VELCADE, VIDA, VYXEOS, XOFICO, YERVOY, YONDELIS, ZALTRAP, ZIRABEV

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 3 months up to 1 year.

OTHER CRITERIA
For initial authorization:
1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For Herceptin Hylecta® (trastuzumab and hyaluronidase-oysk): Documentation of trial and failure,
intolerance, or contraindication to trastuzumab

For reauthorization: documentation of adequate response to the medication must be provided.
INTERLEUKIN – 1 INHIBITORS (ARCALYST, ILARIS)

MEDICATION(S)
ARCALYST, ILARIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Arcalyst® is approved for adults and children 12 years and older.

Ilaris® is approved for 4 years of age and older in patients with CAPS (which includes FCAS, MWS):
Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF

Ilaris® is approved for 2 years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by:
1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1),
AND
2. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold
For Ilaris® only:
For Familial Mediterranean Fever (FMF), and all the following:
1. Documented trial and failure, contraindication or intolerance to colchicine,
   AND
2. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints).

Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by:
1. Laboratory evidence of genetic mutation MVK (mevalonate kinase),
   AND
2. Classic symptoms associated with HIDs (abdominal pain, lymphadenopathy, aphthous ulcers).

Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by:
1. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family),
   AND
2. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations).

Diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA):
1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
   AND
2. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)
MEDICATION(S)
KRSTEXXA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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 up to six months of intermittent long-term therapy.

OTHER CRITERIA
For initial therapy, all of the following criteria must be met:
1) Documentation of frequent and disabling gout flares with history of at least three documented disabling flares in the past 18 months
   AND
2) Documented trial, failure, contraindication or intolerance to the maximum medically appropriate dose of allopurinol.
   AND
3) Documented trial, failure, contraindication or intolerance to probenecid.

Note: an adequate trial and failure is at least one month of continuous therapy
LEMTRADA - MEDICAL BENEFIT

MEDICATION(S)
LEMTRADA

COVERED USES
N/A

EXCLUSION CRITERIA
• In combination with other disease modifying therapy indicated for the treatment of MS
• For treatment beyond 2 years or beyond 2 treatment courses.

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by a Neurologist who has been certified through the Lemtrada® REMS program.

COVERAGE DURATION
Initial authorization will be approved for one year. Reauthorization will be approved for one year. No authorization may be approved for treatment beyond 2 years.

OTHER CRITERIA
1. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis
   AND
2. Documentation of active disease (e.g. patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to at least two of the following disease modifying therapies unless all are contraindicated.
   a. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®)
   b. Interferon-beta 1b (Betaseron®)
   c. Dimethyl fumarate (Tecfidera®)
   d. Glatiramer acetate (Copaxone®)
   e. Natalizumab (Tysabri®)
   f. Teriflunomide (Aubagio®)
   g. Fingolimod (Gilenya®)
Ocrelizumab (Ocrevus®)

Adequate trial is defined as at least 6 months of continuous therapy. Discontinuation of therapy due to drug intolerance will not be considered as failure to therapy.
LUXTURNA - MEDICAL BENEFIT

MEDICATION(S)
LUXTURNA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Results of RPE65 gene test

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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.

OTHER CRITERIA
All of the following must be met:
1. Confirmed biallelic RPE65 gene mutation: and
2. Has not previously had the intended treatment eye treated with gene therapy for retinal dystrophy RPE65 mutations, and
3. Documentation by an ophthalmologist within the previous six (6) 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 greater than 100 ?m thickness shown on optical coherence tomography: and
   b. The member has remaining light perception in the intended treatment eye
MEDICATION(S)
ADVANTAGE, ADVANTAGE WITH IRON NON-GMO, ALFAMINO INFANT, ALFAMINO JUNIOR, ARGIMENT, ARGIMENT AT, ARGINAID, ARGINAID EXTRA, ARGITEIN, BANATROL PLUS, BCAD 1, BCAD 2, BEEF-POTATOES-SPINACH, BENEPROTEIN, BIOTECT PLUS, BOOST LIQUID, BOOST BREEZE, BOOST CALORIE SMART, BOOST COMPACT, BOOST GLUCOSE CONTROL, BOOST HIGH PROTEIN, BOOST KID ESSENTIALS, BOOST KID ESSENTIALS-FIBER, BOOST PLUS, BOOST VHC, CALCILO XD, CERALYTE-70 ELECTROLYTE DRINK, CERASPORT LIQUID, COMPLEAT, COMPLEAT PEDIATRIC, COMPLEAT PEDIATRIC REDUCED CAL, COMPLETE AMINO ACID MIX, COMPLETE NUTRITIONAL, COMPLEX JUNIOR MSD, COMPLEX MSD ESSENTIAL, CULTURELLE KIDS CHEWABLE TAB, CYCLINEX-1, CYCLINEX-2, DECUB-AMINE, DIABETISOURCE AC, DUOCAL, EAA, EGGS-APPLES-OATS, ELECARE, ELECARE JR, ELECTROLYTE, ENFAGROW GENTLEASE FORMULA, ENFAGROW TODDLER NEXT STEP, ENFAGROW TODDLER TRANSITIONS, ENFAGROW TODDLR TRANSITION SOY, ENFAGROW TODDLR NXT STP NON-GMO, ENFAGROW TODDLR TRANSITN NONGMO, ENFAMIL 24, ENFAMIL ENFACARE, ENFAMIL ENFALYTE, ENFAMIL ENSPIRE INFANT FORMULA, ENFAMIL FOR SUPPLEMENTING LIQ, ENFAMIL SUPPLEMENTING NURSETTE, ENFAMIL GENTLEASE LIQUID, ENFAMIL INFANT LIQUID, ENFAMIL INFANT POWDER, ENFAMIL INFANT POWDER PACKET, ENFAMIL INFANT NON-GMO, ENFAMIL NEURO ENFACARE NON-GMO, ENFAMIL NEUROPRO NON-GMO, ENFAMIL NEWBORN, ENFAMIL NEWBORN NON-GMO, ENFAMIL PROSOBEE POWDER, ENFAMIL PROSOBEE LIPIL, ENSURE ACTIVE HEART HEALTH, ENSURE ACTIVE HIGH PROTEIN, ENSURE ACTIVE LIGHT, ENSURE ACTIVE MUSCLE HEALTH, ENSURE ACTIVE PROTEIN-MUSCLE, ENSURE CLEAR, ENSURE CLEAR THERAPEUTIC, ENSURE COMPACT, ENSURE ORIGINAL, ENSURE PLUS, ENSURE POWDER, ENSURE SURGERY, EO28 SPLASH, EQUACARE JR, ESSENTIAL AMINO ACID MIX, FIBERSOURCE HN, FRUITIVITS, G-PREPROTEIN, GA, GA EXPRESS 15, GA GEL, GA-1 ANAMIX EARLY YEARS, GLUCERNA SHAKE, GLUCERNA SNACK SHAKE, GLUCERNA 1 CAL, GLUCERNA 1.2 CAL, GLUCERNA 1.5 CAL, GLUCERNA ADVANCE, GLUCERNA HUNGER SMART, GLUCERNA THERAPEUTIC NUTRITION, GLUTAMENT, GLUTARADE GA-1, GLUTARADE JUNIOR GA-1, GLUTAREX-1, GLUTAREX-2, GLUTASOLVE, GLYCOSADE POWDER PACKET, GLYTACTIN 15 PE BETTERMILK, GLYTACTIN 20PE BETTERMILK LITE, GLYTACTIN BUILD 10 PE, GLYTACTIN BUILD 20-20, 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, GLYTROL, HCU ANAMIX EARLY YEARS, HCU ANAMIX NEXT, HCU COOLER, HCU COOLER20, HCU EXPRESS POWDER, HCU EXPRESS20, HCU GEL, HCU LOPHLEX, HCY 1, HCY 2, HI-CAL LIQUID, HIGH-PROTEIN NUTRITIONAL SHAKE, HOMACTIN AA PLUS 20 PE, HOMINEX-1, HOMINEX-2, I-VALEX-1, I-VALEX-2, IMPACT 1 CAL, IMPACT ADVANCED RECOVERY, IMPACT PEPTIDE 1.5 CAL, INFANT FORMULA WITH IRON, INSTANT FOOD THICKENER, ISOMIL, ISOMIL ADVANCE, ISOMIL DF, ISOSOURCE 1.5 CAL, ISOSOURCE 1.5 CAL
PLUS, PROSOURCE TF, PROSOURCE ZAC, PROTEIN NUTRITIONAL SHAKE, PROTEIN POWDER, PROTEINEX LIQUID, PROVIDE GOLD SUGAR FREE, PROVIMIN, PULMOCARE, PURAMINO DHA-ARA, PURAMINO JR, PURE BLISS, QUINOA-KALE-HEMP, RCF SOY FORMULA, RE-GEN, RELIZORB, RENA START, RENALCAL, RENAMENT, REPLETE, REPLETE WITH FIBER, RESOURCE 2.0, RESOURCE THICKENUP, S.O.S. 15, S.O.S. 20, S.O.S. 25, SALMON-OATS-SQUASH, SCANDISHAKE SINGLE-SERV ENV, SIMILAC ADVANCE LIQUID, SIMILAC ADVANCE POWDER PKT, SIMILAC ADVANCE WITH IRON POWD, SIMILAC ADVANCE LAMEHADRIN, SIMILAC ADVANCE NON-GMO, SIMILAC ADVANCE ORGANIC LIQUID, SIMILAC EXPERT CARE ALIMENTUM, SIMILAC EXPERT CARE DIARRHEA, SIMILAC EXPERT CARE NEOSURE, SIMILAC FOR SPIT-UP POWDER, SIMILAC GO-GROW, SIMILAC GO-GROW SOY, SIMILAC HUMAN MILK FORTIFIER, SIMILAC NEOSURE, SIMILAC PM 60-40, SIMILAC PRO-TOTAL CMFT NON-GMO, SIMILAC SENSITIVE, SIMILAC SENSITIVE FUSS-GAS LIQ, SIMILAC SENSITIVE FUSS-GAS PWD, SIMILAC SOY ISOMIL, SIMILAC SUPPLEMENTATION, SIMILAC TOTAL COMFORT, SIMILAC TOTAL COMFORT NON-GMO, SOD ANAMIX EARLY YEARS, SUPLENA CARB STEADY, THICK AND EASY, THICK NOW, THICK-IT, THICK-IT #2, THICKEN UP CLEAR, TODDLER-INFANT FORMULA, TOLEREX, TURKEY-SWEET POTATOES-PEACHES, TWOCAL HN, TYLACTIN BUILD 20 PE, TYLACTIN RESTORE 10 PE, TYLACTIN RESTORE 5 PE, TYLACTIN RTD 15 PE, TYR ANAMIX EARLY YEARS, TYR ANAMIX NEXT, TYR COOLER, TYR COOLER20, TYR EXPRESS, TYR EXPRESS20, TYR GEL, TYR LOPHLEX, TYR LOPHLEX GMP MIX-IN, TYREX-1, TYREX-2, TYROS 1, TYROS 2, UCD ANAMIX JUNIOR, UCD TRIO, UTYMAX, VILACTIN AA PLUS 20 PE, VITAL 1.0 CAL, VITAL 1.5 CAL, VITAL AF 1.2 CAL, VITAL HIGH NITROGEN, VITAL HIGH PROTEIN, VITAL PEPTIDE 1.5 CAL, VIVONEX, VIVONEX PLUS, VIVONEX RTF, VIVONEX T.E.N, WND 1, WND 2, XLYS, XTRP MAXAMUM, XMET MAXAMUM, XMET XCYS MAXAMAI, XMTVI MAXAMUM, XPHE MAXAMUM, XTRACAL PLUS

**COVERED USES**

Improving nutritional status per criteria below.

**EXCLUSION CRITERIA**

- Milk protein intolerance is not considered an in-born error of metabolism and will not be covered as such.
- 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 Relizorb™ is considered experimental and investigational for use with enteral feedings due to the lack of evidence to assess safety and efficacy on health outcomes

**REQUIRED MEDICAL INFORMATION**

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.
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 may be reviewed annually to assess continued medical necessity and effectiveness of medical food/enteral nutrition.

OTHER 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 7 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 (e.g. 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 3 months or less due to: increased metabolic need resulting from severe trauma, malabsorption difficulties due to underlying medical condition/disease (e.g. 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.

ELEMENTAL FORMULA
FOR INBORN ERRORS OF METABOLISM
ALL of 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 of 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

See Appendix 1 for common nutritional formulas

**REAUTHORIZATION:**
Continued coverage requires documentation that the requested therapeutic regimen is medically necessary to prevent serious disability in the patient
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, CIMZIA 200 MG VIAL KIT, ENTYVIO, ILUMYA, INFLECTRA, ORENCIA 250 MG VIAL, REMICADE, RENFLEXIS, SIMPONI ARIA, STELARA 130 MG/26 ML VIAL, STELARA 45 MG/0.5 ML VIAL

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
•Prior Authorization: Initial authorization will be approved for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
1. For all requests, the patient must have an FDA labeled indication for the requested agent, or use to treat the indication is supported in drug compendia (i.e., American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics’ DRUGDEX® System.)
AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator (TIMs) agent or apremilast (Otezla®) AND

3. One of the following:
   a. For patients already established on the requested TIMs agent (starting on samples will not be considered as established on therapy):
      i. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
   b. Patients not established on the requested TIMs agent must meet ALL of the following indication-specific criteria:
      i. For moderate to severe Ulcerative Colitis:
         1. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®) or vedolizumab (Entyvio®)
      ii. For moderate to severe Crohn’s Disease:
         1. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®)
      iii. For Rheumatoid 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 infliximab (Remicade®) or golimumab IV (Simponi Aria®)
      iv. 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 infliximab (Remicade®)
      v. 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 infliximab (Remicade®) or golimumab IV (Simponi Aria®)
      vi. For Ankylosing Spondylitis:
         1. For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to infliximab (Remicade®) or golimumab IV (Simponi Aria®)
      vii. For giant cell arteritis:
         1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)

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
MIACALCIN

MEDICATION(S)
MIACALCIN 400 UNIT/2 ML VIAL

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

For Treatment of Paget’s Disease:
1. Documentation of trial and failure of bisphosphonate therapy. Failure is defined as no improvement in pain and/or function.

2. Documented contraindication or intolerance to therapy with both of the following:
   a. Oral bisphosphonate (e.g., alendronate)
   b. IV bisphosphonate therapy (i.e., zoledronic acid)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial approval and renewal for 1 year.

OTHER CRITERIA
N/A
MIRCERA - MEDICAL BENEFIT

MEDICATION(S)
MIRCERA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Hemoglobin and Hematocrit levels within 30 days prior to initiation of therapy.
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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

OTHER CRITERIA
For the treatment of adults with anemia associated with chronic kidney disease:
1. Documented Hemoglobin (HGB) levels of less than or equal to 10g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy
2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%

For the treatment of pediatric patients 5 to 17 years of age who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA:
1. Documented hemodialysis for at least 8 weeks
2. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least 8 weeks prior to initiation of therapy
3. Documented stable hemoglobin (HGB) levels for at least 8 weeks prior to initiation of therapy.
Reauthorization:
1. Documentation of continued medical necessity (e.g., ongoing chronic kidney disease)
2. Documented HGB levels of less than or equal to 12g/dl or HCT levels of less than or equal to 36% within previous 30 days
MEDICATION(S)
BYNFEZIA, DARZALEX FASPRO, DURYSTA, FENSOLVI, FETROJA, PHESGO, TRODELVY, UPLIZNA, ZEPZELCA

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
DESCRIPTION:
The Oregon Region Pharmacy & Therapeutics Committee (ORPTC) will make a reasonable effort to review a new chemical entity or new Food and Drug Administration (FDA) indication within 90 days, and will make a decision on each new chemical entity or new FDA indication within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. In some instances, the ORPTC may require an extended amount of time to allow for the availability of sufficient clinical and safety data. New medications or newly approved indications within the six Protected Classes defined by the Centers for Medicare and Medicaid Services (CMS) for Medicare Part D will be subject to an expedited ORPTC review. The ORPTC will make a decision within 90 days, rather than the normal 180-day requirement.

Medications delivered under the supervision of a covered/eligible health care provider are covered under the medical benefit and are also subject to review by the ORPTC. New medical medications and new FDA-approved indications for medical medications are reviewed within 12 months after the medication becomes available on the market, or within 12 months of the approval of a new indication by the FDA. Coverage will be limited to terms and conditions of plan medical benefit. Vaccinations administered under the medical
benefit are subject to benefits and vaccine-specific policy if available.

POLICY:
Medications included under this Prior Authorization Policy may be approved subject to benefit and plan criteria listed below.

If ORPTC reviews a new medication or indication and determines that prior authorization is required, drug specific criteria will be used to evaluate reauthorization request, if applicable.

This policy applies if ORPTC reviews a new medication or indication and defers its decision for a future meeting, or if a request for a medication is received that has not been reviewed by ORPTC.

REQUIRED MEDICAL INFORMATION:
A prior authorization form and relevant chart notes documenting medical rationale are required.

CRITERIA:
To obtain a new medication or an existing medication with a new FDA indication awaiting a decision by the ORPTC, urgency must be established by meeting the following criteria:

1. The medication requested is consistent with the FDA approved indication(s) and evidence-based medicine.
AND
2. One of the following:
a. The medication is considered a new drug entity or an existing drug with a new indication with no effective formulary alternatives available
OR
b. Reasonable trial and failure of suitable formulary alternatives have been documented by the provider in the chart notes.
OR
c. No treatment alternatives are available due to the member being at high risk for or experiencing an adverse drug event. The adverse event risk and prior therapies must be documented. An adverse event is defined as a contraindication, allergy, or sensitivity to the medication.
AND
3. The medication is being prescribed by, or in consultation with, a specialist in the treatment of the condition, or a provider with at least five years of experience treating the condition
AND
4. The prescriber indicates that the patient will experience harm (i.e., worsening clinical outcome and inability to return to baseline, loss of life or limb), if the requested medication is not covered until review by ORPTC
5. For Medicaid (OHP): coverage is limited to a condition that has been designated a covered line item
number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services
MEDICATION(S)
NPLATE

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for up to 3 months. Reauthorization will be approved for up to 6 months.

OTHER CRITERIA
Must meet all of the following:
1. A diagnosis of immune thrombocytopenia (ITP)
   AND
2. Patient is at risk for bleeding with a platelet count of less than 30 x 109/L
   AND
3. Treatment by at least one of the following was ineffective or not tolerated:
   a. Systemic corticosteroids, OR
   b. Immune globulin, OR
   c. Splenectomy

Reauthorization will require submission of platelet values demonstrating a response to therapy and a dose below 10 mcg/kg.
QUANTITY LIMITS:
Nplate is available as 250mcg and 500mcg vials of lyophilized powder. Quantity approved may be rounded down to nearest available vial size within 10% of calculated dose.
OPHTHALMIC VEGF INHIBITORS: EYLEA, LUCENTIS, MACUGEN

MEDICATION(S)
BEOVU, EYLEA, LUCENTIS, MACUGEN

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed and administered by an ophthalmologist or retinal specialist

COVERAGE DURATION
Initial authorization will be approved for one year. Re-authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

OTHER CRITERIA
Initial Authorization:
Must have one of the following diagnoses and meet any required criteria:

1. Neovascular (wet) age-related macular degeneration (AMD)
   For ranibizumab (Lucentis®), aflibercept (Eylea®), brolucizumab (Beovu®)
   a. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
   OR
   b. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for the patient

   For pegaptanib (Macugen®):
   a. Documentation that bevacizumab (Avastin®) and either ranibizumab (Lucentis®) or aflibercept (Eylea®)
has been ineffective, not tolerated, or contraindicated
OR
b. Rationale is provided why therapy is not appropriate for the patient

2. Diabetic macular edema or Diabetic retinopathy
For ranibizumab (Lucentis®) or aflibercept (Eylea®):
 a. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated
   (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
   OR
b. Request is for aflibercept (Eylea®) and patients baseline visual acuity is 20/50 or worse
   OR
 c. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for member

3. Macular edema following retinal vein occlusion
For ranibizumab (Lucentis®) or aflibercept (Eylea®):
 a. Documentation that bevacizumab (Avastin®) has been ineffective, not tolerated, or contraindicated
   (examples of contradictions include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome)
   OR
b. Rationale is provided why therapy with bevacizumab (Avastin®) is not appropriate for the patient

4. Myopic Choroidal Neovascularization (mCNV)
 a. Request is for ranibizumab (Lucentis®)

Reauthorization or continuation of therapy:
Documentation of positive response to therapy (such as stabilization or improvement in vision)

QUANTITY LIMITS: Approval may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines and are subject to medical claims audits. (See Table 1 for dosing guidelines)
PARENTERAL NUTRITION (TPN)

MEDICATION(S)
AMINOSYN, AMINOSYN II, AMINOSYN M, AMINOSYN 7%-ELECTROLYTE SOL, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, CLINIMIX, CLINIMIX E, CLINIMIX N14G30E, CLINIMIX N9G15E, CLINIMIX N9G20E, CLINISOL, FREAMINE HBC, FREAMINE III, HEPATAMINE, INTRALIPID, NEPHRAMINE, NUTRILIPID, OMEGAVEN, PLENAMINE, PREMASOL, PROCALAMINE, PROSOL, SMOFLIPID, SYNTHAMIN 17 WITHOUT ELTYE, TRAVASOL, TROPHAMINE

COVERED USES
N/A

EXCLUSION CRITERIA
Coverage for IDPN when offered in addition to regularly scheduled TPN infusions

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization approved for 3 months and re-authorization will be approved for up to one year.

OTHER CRITERIA
One of the following criteria must be met:
1. Member has a central or peripheral line placed within the past 3 months 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 (i.e. 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.
PREVYMIS

**MEDICATION(S)**
PREVYMIS

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

**AGE RESTRICTION**
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**
3 months, up to 100 days post-transplant

**OTHER CRITERIA**
ALL of the following must be met:
1) Member is within 100 days post-allogeneic transplant: and
2) Cytomegalovirus (CMV) Recipient positive: and
3) Member has ONE of the following:
   a) Graft Versus Host Disease (GVHD) requiring greater than or equal to 1 mg/kg/day use of prednisone [or equivalent]
   b) Receipt of lymphocyte depleting therapy (e.g. antithymocyte globulin [ATG], antithymocyte globulin equine [ATGAM], antithymocyte globulin rabbit [thymoglobulin], alemtuzumab, fludarabine) within the previous 6 months
   c) Transplant was a cord blood allograft
   d) History of CMV drug resistance within the past 6 months
4) If IV lettermovir is being requested, rationale for not using oral formulation must be provided (e.g. patient is unable to swallow)
MEDICATION(S)
PROLIA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BMD T-score. For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess medical necessity and effectiveness of medication.

OTHER CRITERIA
For osteoporosis, must meet all criteria below:
1. Documentation of failure of bisphosphonate therapy (e.g. new fracture or worsening bone mineral density) or contraindication/intolerance to both oral and IV bisphosphonate therapy.
   a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.
   AND
2. One of the following criteria:
   A. Documented clinical diagnosis of osteoporosis (defined as a non-traumatic, non-pathologic spinal fracture or spine or hip bone mineral density (BMD) T-score less than or equal to -2.5)
   OR
   B. Documented risk of osteoporosis (defined as BMD T-score between -1.0 and –2.5) AND meeting one of the following two risk assessments:
   1. One of the following risk factors:
      a. previous fracture
b. history of hip or spine fracture in first degree relative

c. low body weight (less than 127 lbs for women)

d. smoking, excess alcohol intake

e. secondary osteoporosis (e.g. rheumatoid arthritis)

f. history of falls

2. Fracture Risk Assessment (FRAX®) Hip fracture probability greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%

OR

C. One of the following chronic glucocorticosteroid use:

a. greater than 20 mg/day of prednisone or equivalent for longer than 1 month

b. 5-20 mg/day of prednisone or equivalent for longer than 3 months in post-menopausal women not on estrogen

c. 5-20 mg/day of prednisone or equivalent for longer than 3 months AND T-score less than -1.5

For men at high risk of fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer:

1. Documentation of FRAX® hip fracture probability of greater than or equal to 3% or other major osteoporosis fracture probability greater than or equal to 20%. Note that ADT should be considered “secondary osteoporosis” when using the FRAX® algorithm

AND

2. Documentation of trial and failure, contraindication, or intolerance to alendronate or zoledronic acid

a. For patients that have gastrointestinal side effects to alendronate, documentation of trial and failure of zoledronic acid therapy will be required.

For women at high risk of fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:

1. If premenopausal, documentation of failure of bisphosphonate therapy (e.g. new fracture or worsening bone mineral density) or contraindication/intolerance to both oral and IV bisphosphonate therapy.

a. For patients that have gastrointestinal side effects to oral bisphosphonate therapy, documentation of trial and failure of IV bisphosphonate therapy will be required.

2. If postmenopausal (natural or induced), denosumab may be approved
**PROVENGE - MEDICAL BENEFIT**

**MEDICATION(S)**
PROVENGE

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
Concomitant use of chemotherapy and/or immunosuppressive medication with sipuleucel-T is considered experimental/investigational and will not be covered.

**REQUIRED MEDICAL INFORMATION**
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

**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**
All of the following criteria must be met:
1. Asymptomatic or minimally symptomatic metastatic disease (e.g. no complaints of bone pain, no narcotic use for malignant cancer pain)
2. Castrate-resistant or castration-recurrent prostate cancer, defined as both of the following:
   • Radiographic progression despite therapy with androgen ablation therapy (e.g. orchiectomy, GnRH agonists/antagonists)
   AND
   • Testosterone level less than 50 ng/dL
3. No evidence of hepatic metastases
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
5. Life expectancy greater than 6 months
MEDICATION(S)
RADICAVA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Forced vital capacity (FVC), completed ALS Functional Rating Scale-Revised (ALSFRS-R) score form (see Appendix 1) take at baseline and current functional ability in activities of daily living (ADLs)

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months.

OTHER CRITERIA
Initial criteria:
1. Documentation of ALL of the following:
   a. Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) per the El Escorial (Airlie House) Criteria
   b. Diagnosis of ALS within the last 2 years
   c. Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with greater than 2 points in each individual item (Use Appendix 1)
   d. Forced vital capacity (FVC) greater than 80% (taken within the past 3 months)

Reauthorization criteria:
1. Documentation of a clinical benefit from therapy such as stabilization of functional ability and maintenance
2. Patient must not have more than a 6 point decline in the ALSFRS-R from baseline
MEDICATION(S)
REBLOZYL

COVERED USES
N/A

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

For continuation of therapy for beta-thalassemia beyond 9 weeks, ongoing documentation of patient response to therapy must include maintenance of reduced transfusion levels

For initial authorization for myelodysplastic syndrome (MDS), all of the following must be met:
1. Diagnosis of MDS with ring sideroblasts (MDS-RS), or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
2. Score of very low to intermediate risk based on the Revised International Prognostic Scoring System
3. Documentation that patient requires RBC transfusions of at least two (2) units every eight (8) weeks
4. One of the following:
   a. Documented trial and failure, intolerance, or contraindication to erythropoiesis-stimulating agents (i.e., erythropoietin or darbepoetin)
   b. Documentation of endogenous erythropoietin level greater than 200 IU/L

For reauthorization for MDS-RS: Documentation that patient was able to achieve transfusion independence for at least eight weeks during previous treatment period
AGE RESTRICTION
At least 18 years of age

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

COVERAGE DURATION
Beta-thalassemia: Initial authorization will be for 9 weeks. Reauthorization will be for 1 year.
MDS-RS: Initial authorization will be for 6 months. Reauthorization will be for 1 year.

OTHER CRITERIA
N/A
RELISTOR

MEDICATION(S)
RELISTOR

COVERED USES
N/A

EXCLUSION CRITERIA
•Non-opioid induced constipation
•Known or suspected gastrointestinal obstruction not limited to:
oAcute surgical abdomen
oFecal impaction
oAcute diverticular disease

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial authorization and reauthorization for 1 year.

OTHER CRITERIA
1. Patient is on chronic opioid therapy
   AND
2. Documentation of less than 3 spontaneous bowel movements per week
   AND
3. **Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL of the following:
   a. A stimulant laxative (e.g., senna, bisacodyl)
   b. Routine laxative therapy with a different mechanism of action than the laxative above (e.g. lactulose, Miralax®)
   c. One (1) of the following prescription medications
i. Naloxegol (Movantik®)
ii. Lubiprostone (Amitiza®)
iii. Naldemedine (Symproic®)

**For Medicaid, please note that chronic constipation secondary to continuous opioid use as part of a palliative care regimen, or for treatment of active cancer pain, is approvable without meeting criterion #3 only if medical rationale is sufficient**

QUANTITY LIMIT:
8-mg syringe: 1 single use syringe per day (12 ml per 30 days)
12-mg syringe or vial: 1 single use syringe or vial per day (18 ml per 30 days)
150-mg tablet: 3 tablets per day
MEDICATION(S)
RITUXAN, RITUXAN HYCELA, RUXIENCE, TRUXIMA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Oncologic diagnoses:
For initial authorization: use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

For Rheumatoid Arthritis:
1. Documentation of trial, failure, intolerance, or contraindication to two (2) of the following targeted immune modulators: Enbrel®, Humira®, Remicade®, or Simponi® Aria.

AND

2. Documentation that rituximab will be used concurrently with methotrexate. If intolerance or contraindication to methotrexate, then in combination with another DMARD (e.g., leflunomide, sulfasalazine, hydroxychloroquine), unless medical rationale is provided to support monotherapy.

Reauthorization requires documentation of adequate response to therapy.

For Vasculitis – including ANCA-associated vasculitis [e.g., Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)] and refractory polyarteritis nodosa (resistant to cyclophosphamide):
1. Documentation that rituximab will be given in combination with glucocorticoids

AND

2. Documentation of severe disease (e.g., critical organ system involvement)

For Immune Thrombocytopenia (ITP):
1. Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy

AND

2. Documentation of active bleeding, or high-risk of bleeding, or a platelet count less than 30 x 10^9/L

For Relapsing and Remitting Multiple Sclerosis (RRMS):
1. Documentation of trial, failure, intolerance, or contraindication to one (1) injectable disease modifying
agent which include: interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®, Rebif®), glatiramer (Copaxone®, Glatopa®)

AND

2. Documentation of trial, failure, intolerance, or contraindication to at least two (2) oral preferred disease modifying agents which include: dimethyl fumarate (Tecfidera®), fingolimod (Gilenya®), teriflunomide (Aubagio®)

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

For Autoimmune Hemolytic Anemia (AIHA):
1. In patients diagnosed with warm AIHA
   a. Documentation of trial, failure, intolerance, or contraindication to glucocorticoids
      AND
   b. Documentation that the patient is unable to achieve remission with splenectomy unless the patient is not a candidate for surgery
   OR
   2. In patients diagnosed with cold AIHA or cold agglutinin disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an oncologist, rheumatologist, neurologist (in the case of RRMS, NMO), dermatologist (in the case of PV), or nephrologist (in the case of renal disease).

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

OTHER CRITERIA
N/A
MEDICATION(S)
OCTREOTIDE ACETATE, SANDOSTATIN, SANDOSTATIN LAR, SANDOSTATIN LAR DEPOT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Safety and efficacy has not been established in the pediatric population

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Variceal bleeding: One (1) month
Other indications: Initial authorization and reauthorization for 12 months

OTHER CRITERIA
Acromegaly:
Initial authorization
1. Confirmed diagnosis of acromegaly
2. Documentation of an inadequate response to surgery or pituitary irradiation or patient is not a candidate for surgical resection and pituitary irradiation
3. History of failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses
4. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy
Re-authorization:
1. Documentation of a positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)
Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing:
Initial authorization
1. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
2. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:
1. Documentation of an improvement in the number of diarrhea and flushing episodes

Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea:
Initial authorization
1. Documentation that patient has severe diarrhea caused by a vasoactive intestinal peptide tumors
2. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:
1. Documentation of an improvement in the number of diarrhea episodes

For chemotherapy induced diarrhea:
Initial authorization
1. Documentation that patient has severe diarrhea caused by chemotherapy
2. Documentation of an inadequate response or contraindication to loperamide
3. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:
1. Documentation of an improvement in the number of diarrhea episodes

For AIDS-related diarrhea:
Initial authorization
1. Documentation that patient has severe diarrhea
2. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate (Lomotil®)
3. For Sandostatin LAR, patient has had a trial of short-acting octreotide and responded to and tolerated therapy

Re-authorization:
1. Documentation of an improvement in the number of diarrhea episodes

For variceal bleeding:
1. Documentation of variceal bleeding
2. Documentation that therapy will be used short term (less than 1 month)

Note: Short-term treatment of acute bleeding of gastroesophageal varicities will be covered for one month of
therapy only. Use beyond one month is not considered medically necessary.

For oncologic diagnoses:
For initial authorization: use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.
MEDICATION(S)
SCENESSE

COVERED USES
N/A

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

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

For reauthorization:
1. Documentation of a positive response to therapy by one of the following:
   a. Decreased severity and number of phototoxic reactions
   b. Increased duration of sun exposure
   c. Increased quality of life
2. For request of more than 3 implants per year: medical justification must be provided addressing why member needs coverage for more than 6 months out of the year (afamelanotide is typically given during periods of high sunlight exposure, e.g. from spring to autumn)

AGE RESTRICTION
Approved for 18 years of age or older

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with a dermatologist or porphyria specialist
COVERAGE DURATION
Initial and reauthorization will be approved for 6 months for 3 implants (Medical justification is required for requests beyond 3 implants for seasonal coverage)

OTHER CRITERIA
N/A
SIGNIFOR LAR - MEDICAL BENEFIT

MEDICATION(S)
SIGNIFOR LAR

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

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

OTHER CRITERIA
Treatment of patients with acromegaly:
1. Documentation that the patient has persistent, moderate-to-severe symptoms of acromegaly (e.g., impaired glucose tolerance, hypertension, elevated triglycerides, arrhythmias) following surgical resection: or patient is ineligible for surgery
   AND
2. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy

Note: Mild symptoms of disease are typically treated with a dopamine agonist (e.g., cabergoline)

Patients with Cushing’s disease:
1. Diagnosis of endogenous Cushing’s Disease
   AND
2. Documentation of one of the following:
   a. Patient has failed pituitary surgery or
b. Patient is not a candidate for surgery

Reauthorization:

Acromegaly: documentation of response to therapy, as defined as normalization of insulin-like growth factor (IGF)-1 and reduction of symptoms

Cushing’s disease: documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)
SOLIRIS - MEDICAL BENEFIT

MEDICATION(S)
SOLIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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 3 months and reauthorization will be approved for up to one year.

OTHER CRITERIA
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 least two independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
   AND
2. Severe disease as indicated by at least one of the following (a or b):
   a. Documented history of thrombosis, OR
   b. Documentation of at least 10% PNH type III red cells AND at least one of the following:
      i. Transfusion dependence (eg. hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
      ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (e.g. dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

Reauthorization for PNH: documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms

For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
1. Diagnosis of non-infections HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)
   AND
2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
   AND
3. Complement dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD): the activatory genes: factor B (CFB) and C3 and autoantibodies to CFH)
   AND
4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions)

Reauthorization for HUS: documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
• Maintenance of platelet counts (i.e. improvements or reductions less than 25%)
• Reductions in LDH
• Reduction in number of needed plasmapheresis or plasma infusion events
• Improvement in kidney function and reduction of dialysis

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 5
   AND
4. Failed treatment for at least 1 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 4 infusions/ year of either intravenous immunoglobulin (IVIg) OR plasma exchange (PE)
Reauthorization for Myasthenia Gravis (MG): initial reauthorization may require documentation of improvement in MG-ADL by at least 2 points from baseline.

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

2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis)

3. Trial and failure, intolerance or contraindication to rituximab

Reauthorization for Neuromyelitis Optica Spectrum Disorder (NMOSD): Documentation of positive clinical response to therapy
SPINRAZA - MEDICAL BENEFIT

MEDICATION(S)
SPINRAZA

COVERED USES
N/A

EXCLUSION CRITERIA
Concomitant use with, or following, gene therapy for SMA (e.g., onasemnogene abeparvovec)

REQUIRED MEDICAL INFORMATION
Genetic test results ("survival motor neuron (SMN)1 gene testing"/"spinal muscular atrophy (SMA) diagnostic test")

Documentation of baseline motor function, with a standardized test deemed appropriate based on the patient’s age and level of function: CHOP-INTEND, HINE, HFMSE, RULM, or 6MWT

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 12 months.

OTHER CRITERIA
1. Diagnosis of Spinal Muscular Atrophy w/ genetic testing confirmation
   AND
2. Patient is presymptomatic or has symptoms with an onset at age less than 30 years
   AND
3. Documentation of baseline motor function, with a standardized test appropriate based on the patient’s age and level of function: CHOP-INTEND, HINE, HFMSE, RULM, or 6MWT

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

CHOP-INTEND: Children’s hospital of Philadelphia Infant Test of Neuromuscular Disorders
HINE: Hammersmith Infant Neurological Examination
HFSME: Hammersmith Functional Motor Scale Expanded
6MWT: six-minute walk test
RULM: Revised Upper Limb Module

Reauthorization: Improvement or maintenance of motor function, evidenced by follow-up results of motor function test performed at baseline
SPRAVATO

MEDICATION(S)
SPRAVATO

COVERED USES
N/A

EXCLUSION CRITERIA
• 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 6 months) of moderate or severe substance or alcohol use disorder

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years and older

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 6 months

OTHER CRITERIA
For initial authorization all of the following criteria must be met:
1. Individual has been diagnosed with major depressive disorder (MDD) and has been evaluated by a psychiatrist or psychiatric nurse practitioner within the previous 3 months
2. Individual has a Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28
3. Individual has tried and failed three oral antidepressants in at least two different therapeutic classes for at least 8 weeks of treatment at the highest tolerable dose or the FDA-approved maximum dose for the
medication
4. Individual has tried and failed augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly)
5. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy
6. Dosing is in accordance with the United States Food and Drug Administration approved labeling

For reauthorization, all of the following criteria must be met:
1. Documentation of clinical improvement in depression symptoms as measured by a significant decrease in MADRS score
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
MEDICATION(S)
SYLVANT

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for 1 year.

OTHER CRITERIA
1. Confirmed diagnosis of Multicentric Castleman Disease (MCD)
   AND
2. Documentation of negative human immunodeficiency virus (HIV) status
   AND
3. Documentation of negative human herpes-virus 8 (HHV-8) status

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

MEDICATION(S)
TEPEZZA

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

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

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

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Authorization will be approved for six (6) months for a total of eight (8) infusions
OTHER CRITERIA
N/A
TESTOSTERONE REPLACEMENT THERAPY (TRT)

MEDICATION(S)
ANDRODERM, ANDROGEL 1.62% GEL PUMP, ANDROGEL 1.62%(1.25G) GEL PCKT, ANDROGEL 1.62%(2.5G) GEL PCKT, AVEED, AXIRON, FORTESTA, JATENZO, NATESTO, STRIANT, TESTOPEL, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 30 MG/1.5 ML PUMP, XYOSTED

COVERED USES
N/A

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

Medicaid only:
The procedure to implant Testopel® is not a covered benefit and therefore, the drug itself will not be covered.

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication

OTHER CRITERIA
For patients established on testosterone replacement therapy:
1. Documented trial and failure of generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms

For initiation of testosterone replacement therapy, all of the following criteria must be met:
1. Documentation of trial and failure, contraindication or intolerance to generic topical testosterone 1%. Failure is defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms: AND
2. One of the following:
   a. Diagnosis of gender dysphoria or gender identity disorder
   OR
   b. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism: AND confirmatory laboratory values, as outlined below, taken before 11 am, or within 3 hours of waking for shift-workers, on different days without acute illness/stress, according to the local laboratory’s lower limit of normal (if available) or levels according to the listed values below:
      i. At least two (2) serum total testosterone levels less than 264 ng/dL (9.2 nmol/L) OR
      ii. At least two (2) free testosterone levels less than 2 ng/dL (20 pg/mL) OR
      iii. At least one (1) serum total testosterone level less than 264 ng/dL (9.2 nmol/L) AND one (1) free testosterone levels less than 2 ng/ dL (20 pg/mL). Serum total testosterone level and free testosterone level must be taken on different days.
TRANSTHYRETIN (TTR) LOWERING AGENTS

MEDICATION(S)
ONPATTRO, TEGSEDI

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
• Genetic test results (TTR gene testing documenting mutation)
• Documentation of baseline polyneuropathy and impairment demonstrated by the following three (3) standardized tools:
  1. Polyneuropathy disability (PND) score OR familial amyloid polyneuropathy (FAP) stage
  2. Neuropathy impairment score (NIS)
  3. Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for patients 18 years of age and older

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

COVERAGE DURATION
Initial authorization will be approved for 6 months
Reauthorization will be approved for 12 months
OTHER CRITERIA
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 ? IIIB OR has a baseline familial amyloid
   polyneuropathy (FAP) stage of I or II
   AND
4. Baseline neuropathy impairment score (NIS) between 5 and 130
   AND
5. Baseline Norfolk Quality of Life-Diabetic Neuropathy Questionnaire (Norfolk-QOL-DN) score
   AND
6. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two of
   the following:
   • Peripheral sensorimotor polyneuropathy (e.g., tingling or increased pain in the hands, feet, hands and/or
     arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome,
     loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
   • Autonomic neuropathy symptoms (e.g., orthostasis, abnormal sweating, sexual dysfunction, recurrent
     urinary tract infection, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early
     satiety])
   AND
7. For patisiran (Onpattro®): Not taking in combination with inotersen (Tegsedi®) or tafamidis
   OR
   For inotersen (Tegsedi®): Not taking in combination with patisiran (Onpattro®) or tafamidis

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

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

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, viral load, resistance testing and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary as well as viral load.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year.

OTHER CRITERIA
Initial Authorization:
1. Inadequate response to six (6) months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last 8 weeks
   a. Defined as persistent viremic failure
   b. Failure must not be due to non-adherence (adherence may be verified by pharmacy claims)
2. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance to at least one antiretroviral medication from each of the three (3) following classes:
   a. Non-nucleoside reverse transcriptase inhibitor
   b. Nucleoside reverse transcriptase inhibitor
   c. Protease inhibitor
3. Documentation of baseline viral load
4. Confirmation that patient will take an optimized background regimen of anti-retroviral therapy (ART) along with Trogarzo™ therapy
Re-authorization or continuation of therapy:
1. Patient has previously received treatment with Trogarzo™.
2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy)
3. Confirmation that patient will continue to take an optimized background regimen of anti-retroviral therapy (ART) with Trogarzo™ therapy
TYMLOS

MEDICATION(S)
TYMLOS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BMD T-score, FRAX.

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

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

COVERAGE DURATION
May be approved for up to 2 years, ensuring the cumulative duration of osteoanabolic therapy does not exceed 2 years in a lifetime. Duration of osteoanabolic therapy is defined as cumulative duration spent on any of the three therapies: abaloparatide, teriparatide, or romosozumab.

OTHER CRITERIA
For the treatment or prevention of osteoporosis, must meet ONE of the following criteria:
1. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures
2. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 and high risk for fracture, defined as one of the following:
   a. Age more than 80 years
   b. Chronic glucocorticoid use
   c. Documented increased fall risk
3. Patient has a spine or hip BMD T-score less than or equal to -2.5 and one of the following:
   a. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy
b. Documented contraindication or intolerance to therapy with all of the following: 1. denosumab, 2. oral bisphosphonate (e.g., alendronate), and 3. IV bisphosphonate therapy (i.e., zoledronic acid).

4. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following:
   a. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%.
   b. One of the following:
      i. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while adherent to therapy.
      ii. Documented contraindication or intolerance to therapy with all of the following:
         1. Denosumab
         2. Oral bisphosphonate (e.g., alendronate)
         3. IV bisphosphonate therapy (i.e., zoledronic acid)
MEDICATION(S)
TYSABRI

COVERED USES
N/A

EXCLUSION CRITERIA
Use of Tysabri® in combination with other disease modifying therapy to treat patients with multiple sclerosis will not be covered.
In Crohn’s disease, the use of Tysabri® in combination with immunosuppressants or inhibitors of TNF-? will not be covered.

REQUIRED MEDICAL INFORMATION
Anti-JCV antibody

For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by either a Neurologist or Gastroenterologist

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

OTHER CRITERIA
For Multiple Sclerosis:
1. Clinical diagnosis of a relapsing form of multiple sclerosis
   AND
2. One of the following:
   a. Documentation of trial, failure, or intolerance to at least two of the following disease modifying therapies: interferon beta-1a (Avonex®, Rebif®), peginterferon beta-1a (Plegridy®), interferon-beta 1b (Betaseron®), dimethyl fumarate (Tecfidera®), glatiramer acetate (Copaxone®), teriflunomide (Aubagio®), or fingolimod (Gilenya®)
   OR
b. Documentation that patient has highly active or aggressive disease
AND
3. Negative anti-JCV antibody status OR if anti-JCV antibody positive, the patient must meet the following criteria:
   a. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil
   AND
   b. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

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

For reauthorization: Documentation of response to therapy must be provided
ULTOMIRIS

MEDICATION(S)
ULTOMIRIS

COVERED USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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

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

COVERAGE DURATION
Initial authorization for up to 3 months and reauthorization will be approved for up to one year.

OTHER CRITERIA
Paroxysmal Nocturnal Hemoglobinuria (PNH):

Initial authorization all of the following must be met:
1.Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64)
2 Severe disease as indicated by at least one of the following (a or b):
 a.Documented history of thrombosis, OR
 b. Documentation of at least 10% PNH type III red cells AND at least one of the following:
  i. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
ii. Disabling fatigue
iii. End-organ complications
iv. Frequent pain paroxysms (e.g., dysphagia or abdominal pain)
v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:
Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1 above) and severe disease (criteria 2 above). However, this can be based on patient's history prior to starting eculizumab.

Reauthorization:
Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms

Compliment-Mediated Hemolytic Uremic Syndrome (HUS)
Initial authorization all of the following must be met:
1. Diagnosis of non-infectious HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)
   AND
2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
   AND
3. Compliment dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD): the activator genes: factor B (CFB) and C3 and autoantibodies to CFH)
   AND
4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions)

For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®)
Confirmed documentation of Compliment-Mediated Hemolytic Uremic Syndrome (criteria 1, 2 and 3). However, this can be based on patient’s history prior to starting eculizumab.

Reauthorization for HUS: documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:
• Maintenance of platelet counts (i.e. improvements or reductions less than 25%)
• Reductions in LDH
• Reduction in number of needed plasmaphoresis or plasma infusion events
• Improvement in kidney function and reduction of dialysis
MEDICATION(S)
XOLAIR

COVERED USES
N/A

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

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 3 months patient is adherent to a combination of a 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 2 exacerbations requiring oral systemic corticosteroids in the last 12 months
   c. At least 1 exacerbation requiring hospitalization

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses

For chronic idiopathic urticaria, must meet all of the following criteria:
1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out
   AND
2. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine)
   AND
3. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (e.g., montelukast), first generation H1 antihistamine (e.g., diphenhydramine), or histamine H2-receptor antagonist (e.g., famotidine, ranitidine)
Reauthorization for chronic idiopathic urticaria will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose).

**AGE RESTRICTION**
Treatment of asthma: Approved for 6 years of age or older.
Treatment of urticaria: Approved for 12 years of age or older

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

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

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

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

COVERED USES
N/A

EXCLUSION CRITERIA
Patients with existing heart failure

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
Approved for 18 years of age and older

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

COVERAGE DURATION
Initial authorization and reauthorization will be approved for a one-time intravenous dose at 10 mg/kg.

OTHER CRITERIA
All of the following criteria must be met for Clostridium difficile infection (CDI):
1. Must be used in combination with standard-of-care antibiotics for treatment (e.g., oral vancomycin, fidaxomicin, metronidazole)

AND
2. One of the following:
   a. At least three episodes of mild to moderate CDI that have not responded to six to eight weeks of treatment with standard-of-care antibiotics, including an oral vancomycin taper
   b. Have had at least two episodes of severe CDI that required them to be admitted to the hospital

Reauthorization requires:
1. Previous dose was at least six (6) months ago

AND
2. Patient must have had documented benefit from previous infusion, defined as reduction in frequency of recurrences of CDI from baseline
ZOLGENSMA

MEDICATION(S)
ZOLGENSMA

COVERED USES
N/A

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

REQUIRED MEDICAL INFORMATION
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTION
May be covered for patients 2 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
1. Confirmed genetic diagnosis of SMA with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to 3 copies of SMN2
   a. For patients with 3 copies of SMN2, documentation of clinical symptoms of disease is required
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 ≥ 1:50
4. Documentation of baseline tests for liver function, platelet count, and troponin-I
**MEDICATION(S)**
ZULRESSO

**COVERED USES**
N/A

**EXCLUSION CRITERIA**
Active psychosis or a history of bipolar disorder

**REQUIRED MEDICAL INFORMATION**
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

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

**PRESCRIBER RESTRICTION**
Must be prescribed by or in consultation with a psychiatrist or psychiatric nurse practitioner

**COVERAGE DURATION**
Authorization will be approved for 1 month for a one-time infusion. Treatment is limited to one infusion per pregnancy. Re-authorization for the same post-partum period will not be permitted. Authorization for subsequent pregnancies may be allowed when criteria outlined in the policy is met

**OTHER CRITERIA**
1. Patient has a confirmed diagnosis of postpartum depression (PPD)
2. The patient had an onset of depressive symptoms no sooner than the third trimester of pregnancy and no later than within 4 weeks after delivery
3. The patient is less than 6 months postpartum
4. Negative pregnancy test result
5. Patient has documentation of severe postpartum depression based on the Hamilton Rating Scale for Depression (HAM-D) or another standardized, validated depression tool or documentation of suicidal ideation
6. Individual has failed at least 6 weeks of oral anti-depressant therapy or documentation that a trial would be inappropriate or cause harm