Appendix B: Physician Administered Drug (PAD) Criteria

Effective 07/23/2026, Version 2

To view the Virginia Medicaid Preferred Drug List and the Cytokine and CAM Antagonist Appendix A, please use the following link: Virginia Medicaid Preferred Drug List/Common Core Formulary

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ABECMA® (IDECABTAGENE VICLEUCEL)

HCPCS: Q2055

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received prior CAR-T cell therapy; **AND**
- Member does not have an active infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during idecabtagene vicleucel treatment, and until immune recovery following treatment; **AND**
- Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Member does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant CNS pathology; **AND**
- Member does not have active or a history of plasma cell leukemia; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with idecabtagene vicleucel; **AND**

Multiple Myeloma

- Member has relapsed or refractory disease; **AND**
  - Member has received at least two (2) prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab); **OR**
  - Member has received at least three (3) prior lines of therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 dose of up to 510 million autologous CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal.

ACTEMRA® (TOCILIZUMAB)

HCPCS: J3262

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Subcutaneous

- 162 billable units every 7 days

Intravenous

- Cytokine Release Syndrome: 3200 billable units
- All other indications: 800 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ADAKVEO® (CRIZANLIZUMAB-TMCA)

HCPCS: J0791

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Medication is prescribed by or in consultation with an oncologist, hematologist, or sickle cell specialist; **AND**
- Member has a diagnosis of sickle cell disease presenting as one of following: HbSS, HbSC, HbSβ⁰-thalassemia, or HbSβ⁺-thalassemia; **AND**
- Member has had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant); **AND**
- Medication dose is proper for the member's age or other conditions affecting the dose, according to the FDA-approved product package insert; **AND**
- Member has experienced two or more vaso-occlusive crises (VOC) in the previous year, despite hydroxyurea therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member's response compared to pre-treatment baseline is evidenced by a decrease in the frequency of vaso-occlusive crises (VOC) necessitating treatment, reduction in number or duration of hospitalizations, and/or reduction in severity of VOC.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

120 billable units at weeks 0, 2, and every 4 weeks thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ADCETRIS® (BRENTUXIMAB VEDOTIN)

HCPCS: J9042

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member must not be receiving concomitant bleomycin; **AND**
- Member does not have severe renal impairment (i.e., CrCl <30 mL/min); **AND**
- Member does not have moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment; **AND**
- Member has CD30-positive disease; **AND**
- Member meets indication specific criteria below:

Adult Classic Hodgkin Lymphoma (cHL)

- Used as single agent therapy; **AND**
  - Used as consolidation/maintenance therapy post-autologous hematopoietic stem cell transplant (auto-HSCT) in members at high risk for relapse or progression; **OR**
  - Member has relapsed disease after failure of auto-HSCT or after failure of at least 2 (two) prior multi-agent chemotherapy regimens in members who are not auto-HSCT candidates; **OR**
- Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD); **AND**
  - Used as initial therapy for previously untreated stage III or IV disease.

Pediatric Classic Hodgkin Lymphoma (cHL)

- Member is at least 2 years of age or older; **AND**
  - Used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide in members with previously untreated high risk disease.

T-Cell Lymphomas

- Peripheral T-Cell Lymphomas (PTCL)
  - Used for relapsed or refractory disease as subsequent therapy after failure of at least one prior multi-agent chemotherapy regimen in members with Systemic Anaplastic Large Cell Lymphoma (sALCL); **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) as initial therapy for previously untreated:
    - Systemic Anaplastic Large Cell Lymphoma (sALCL)
    - Peripheral T-Cell Lymphoma not otherwise specified (PTCL-NOS)
    - Angioimmunoblastic T-cell Lymphoma (AITL)

Primary Cutaneous Lymphomas

- Mycosis Fungoides (MF)
  - Used as single agent systemic therapy; **AND**
    - Used as subsequent therapy

- Primary Cutaneous Anaplastic Large Cell Lymphoma
  - Used as subsequent therapy

B-Cell Lymphomas

- Large B-Cell Lymphoma, including Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified, DLBCL arising from indolent lymphoma, or High Grade B-Cell Lymphomas (HGBL)
  - Used after two or more lines of systemic therapy for relapsed/refractory disease; **AND**
  - Member is not eligible for autologous hematopoietic stem cell transplantation or CAR T-cell therapy; **AND**
  - Used in combination with lenalidomide and a rituximab product.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member has been evaluated for the presence of progressive multifocal leukoencephalopathy (PML) and has been found to be negative.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Classical Hodgkin Lymphoma:

- 1350 billable units every 84 days

All other indications:

- 200 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ADSTILADRIN® (NADOFARAGENE FIRADENOVEC-VNCG)

HCPCS: J9029

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a hypersensitivity to interferon alfa; **AND**
- Member is not immunosuppressed or immunodeficient; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**
- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) (with or without papillary tumors); **AND**
- Member has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) (defined as persistent disease following adequate BCG therapy**, disease recurrence after an initial tumor-free state following adequate BCG therapy**, or T1 disease following a single induction course of BCG); **AND**
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**
- Member does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma.

**Note: Adequate BCG therapy is defined as at least 5 of 6 induction doses plus either of: at least 2 doses of maintenance therapy or of 2nd induction therapy

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
  - For first renewal only: Member has a complete response (CR) to initial therapy (after 3 months) defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR**
  - For subsequent renewals: Member has not experienced a high-grade or CIS recurrence.

QUANTITY LIMITS (I BILLABLE UNIT = 1 DOSE)

1 billable unit every 3 months

LENGTH OF AUTHORIZATION

3 months for initial approval, 6 months for renewal

ADZYNMA® (ADAMTS13, RECOMBINANT-KRHN)

HCPCS: J7171

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age; **AND**
- Member has not been diagnosed with other congenital thrombotic thrombocytopenic purpura (cTTP) like disorders (e.g., acquired TTP, immune TTP, other primary thrombotic microangiopathies, immune thrombocytopenia, Evans Syndrome, etc.); **AND**
- Member does not have a medical history or the presence of functional ADAMTS13 inhibitors prior to the start of therapy; **AND**
- Member has a documented diagnosis of severe hereditary ADAMTS13 deficiency, confirmed by molecular genetic testing documenting biallelic pathogenic variants in ADAMTS13; **AND**
- Member has an ADAMTS13 activity of less than 10% as measured by the fluorescent resonance energy transfer- von Willebrand factor73 (FRETS-VWF73) assay (Note: Members currently receiving prophylactic plasma infusion therapy may exceed 10% ADAMTS13 activity at start of therapy); **AND**
  - Treatment will be used as prophylactic therapy; **AND**
    - Member has a history of at least one TTP event or is currently receiving prophylactic plasma infusion therapy (Note: Patients who have been receiving prophylactic plasma-based therapies should discontinue routine use of those therapies after achieving a therapeutic response); **OR**
  - Treatment will be used as on-demand therapy and member is at risk of a disease exacerbation

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 UNITS)

1800 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

AFLIBERCEPT - INTRAVITREAL

HCPCS: J0177, J0178, Q5147

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age, unless otherwise specified; **AND**
- Member is free of ocular and/or peri-ocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment (Note: NOT applicable to members with Retinopathy of Prematurity); **AND**
- Member has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD); **OR**
  - Macular Edema following Retinal Vein Occlusion (RVO); **OR**
  - Diabetic Macular Edema (DME); **OR**
  - Diabetic Retinopathy (DR); **OR**
  - Retinopathy of Prematurity (ROP) (Note: NOT applicable to Eylea HD); **AND**
    - Member is a premature infant with a maximum gestational age at birth of 32 weeks or a birth weight of 800 to 1500 g

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- **Eylea, Pavblu:**
  - nAMD, RVO, DME/DR: 4 units every 28 days
  - ROP: 4 units initially, then 4 units every 10 days for 2 additional doses
- **Eylea HD:**
  - 16 units every 25 days

LENGTH OF AUTHORIZATION

- Initial: 12 months, unless otherwise specified.
  - Retinopathy of Prematurity (ROP): Prior authorization validity will be provided initially for a total of 2 doses (1 dose per eye)
- Renewal: 12 months, unless otherwise specified.
  - Retinopathy of Prematurity (ROP): Prior authorization validity may be renewed as re-treatment for up to an additional 4 doses (2 doses per eye)

AKYNZEO® (FOSNETUPITANT/PALONOSETRON)

HCPCS: J1454

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = FOSNETUPITANT 235MG AND PALONOSETRON 0.25 MG)

1 billable unit every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

ALDURAZYME® (LARONIDASE)

HCPCS: J1931

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 6 months of age; **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG) has been obtained; **AND**
- Documented baseline age-appropriate values for one or more of the following have been obtained:
  - Members 6 years of age or older: percent predicted forced vital capacity (FVC), 6-minute walk test (6-MWT), joint range of motion, left ventricular hypertrophy, growth, and/or quality of life (CHAQ/HAQ/MPS HAQ); **OR**
  - Members 6 months to less than 6 years of age: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-MWT; **AND**
- Therapy is being used to treat non-central nervous system manifestations of the disease and member does not have severe, irreversible cognitive impairment; **AND**
- Member has a definitive diagnosis of Mucopolysaccharidosis I as confirmed by one of the following:
  - Detection of biallelic pathogenic mutations in the α-L-iduronidase (IDUA) gene by molecular genetic testing; **OR**
  - Detection of deficient activity of the IDUA lysosomal enzyme; **AND**
- Member has one of the following diagnoses:
  - Hurler (severe) or Hurler-Scheie (attenuated) forms of disease; **OR**
  - Scheie (attenuated) form of disease with moderate to severe symptoms

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

2668 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

ALIQOPA® (COPANLISIB)

HCPCS: J9057

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of relapsed Follicular Lymphoma; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy after at least two (2) prior therapies.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

180 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

ALPHA-1-PROTEINASE INHIBITORS*

HCPCS: J0256, J0257

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have immunoglobulin-A (IgA) deficiency with antibodies against IgA; **AND**
- Member has an FEV1 in the range of 30-65% of predicted; **AND**
- Member has alpha-1-antitrypsin (AAT) deficiency with PiZZ, PiZ (null), or Pi (null, null) phenotypes; **AND**
- Member has clinical evidence of panacinar/panlobular emphysema or centrilobular emphysema; **AND**
- Member has low serum concentration of AAT ≤ 57 mg/dL (measured by nephelometry) or ≤ 11 µM/L (measured by ELISA); **AND**
- Member is receiving optimal medical therapy (e.g., comprehensive case management, pulmonary rehabilitation, vaccinations, smoking cessation, self-management skills, etc.).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

2800 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

*Alpha-1-proteinase inhibitors include: Aralast NP®, Glassia®, Prolastin®-C, and Zemaira®

AMONDYS-45 (CASIMERSEN)

HCPCS: J1426

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a confirmed diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping; **AND**
- Member has been on a stable dose of corticosteroids (unless contraindicated or intolerant); **AND**
- Member will not be using any other exon skipping agents for DMD.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

1400 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

AMVUTTRA® (VUTRISIRAN)

HCPCS: J0225

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing or stabilizing agents (e.g., tafamidis, patisiran, acoramidis, etc.); **AND**

Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis

- Member has a definitive diagnosis of hATTR amyloidosis as identified by molecular genetic testing; **AND**
- Used for the treatment of polyneuropathy as demonstrated by at least two of the following criteria:
  - Subjective patient symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; **AND**
- Member's peripheral neuropathy is attributed to hATTR and other causes of neuropathy have been excluded; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.); **AND**
- Member has not been the recipient of an orthotopic liver transplant (OLT)

Cardiomyopathy of Wild Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM)

- Member has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness greater than 12 mm; **AND**
- Member has a definitive diagnosis of Wild Type or Hereditary ATTR-CM as confirmed by laboratory testing (e.g., stannous pyrophosphate [PYP] scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing [TTR genotyping]); **AND**
  - Member has a medical history of heart failure which required at least 1 prior hospitalization; **OR**
  - Member has clinical evidence of heart failure (with or without hospitalization) manifested by signs and symptoms of volume overload or elevated intracardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic; **AND**
- Member has New York Heart Association (NYHA) Class I or II heart failure OR Class III heart failure that is not considered high risk (i.e., excludes members with NYHA high risk Class III disease and Class IV disease); **AND**
- Member has a baseline 6-minute walk-test (6MWT) distance of at least 150 meters.

RENEWAL CRITERIA

- Member continues to meet the universal and other indication-specific relevant criteria identified above; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ocular symptoms related to vitamin A deficiency (e.g., night blindness), etc.; **AND**

Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis

- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Signs and symptoms of neuropathy
  - MRC muscle strength

Cardiomyopathy of Wild Type Transthyretin-Mediated Amyloidosis (ATTR-CM)

- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Frequency of cardiovascular-related hospitalizations or urgent heart failure visits
  - Total distance walked during 6-minute walk test (6MWT).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

25 billable units every 3 months

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal.

ANDEMBRY® (GARADACIMAB-GXII)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used for prophylaxis of hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Member has tried and failed the preferred product Cinryze (C1 esterase inhibitor).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS

400 mg loading dose followed by 200 mg once monthly

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ANKTIVA® (NOGAPENDEKIN ALFA INBAKICEPT-PMLN)

HCPCS: J9028

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) (with or without papillary tumors); **AND**
- Member has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) (defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of completion of adequate BCG therapy**); **AND**
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components) (Note: Members with residual CIS that is not amenable to complete resection, fulguration, or cauterization is permitted); **AND**
- Member does NOT have muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e., urethra, ureter, or renal pelvis) bladder cancer.

****Note:** Adequate BCG therapy is defined as ≥ 5 of 6 induction doses plus either ≥ 2 doses of maintenance therapy or of 2nd induction therapy

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

- Induction: 400 billable units once weekly up to 12 doses.
- Maintenance: 400 billable units once weekly for three weeks at months 4, 7, 10, 13, 19, 25, 31, and 37 (total of 24 doses).

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal up to a maximum of 37 months of therapy (i.e., up to a total of 36 doses)

APHEXDA® (MOTIXAFORTIDE)

HCPCS: J2277

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member will not use in combination with other chemokine receptor 4 (CXCR4) antagonists; **AND**
- Used for autologous transplantation in multiple myeloma members; **AND**
- Used in combination with filgrastim (or its biosimilars) or tbo-filgrastim.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.25 MG)

496 billable units per dose for up to two doses, separated by at least 2 days

LENGTH OF AUTHORIZATION

One treatment consisting of two doses, not eligible for renewal

APONVIE® (APREPITANT)

HCPCS: J8502

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Clinical evidence is provided that preferred antiemetic/antivertigo agents on the PDL will not provide adequate benefit, including what pharmaceutical agents have already been attempted and the outcomes of those trials, where applicable.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

32 billable units

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal.

ARANESP® (DARBEPOETIN ALFA, NON-ESRD)

HCPCS: J0881

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has tried and failed two preferred erythropoiesis stimulating agents (see Erythropoiesis Stimulating Proteins on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

600 billable units

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ARCALYST® (RILONACEPT)

HCPCS: J2793

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Cryopyrin-Associated Periodic Syndromes (CAPS), Recurrent Pericarditis

- 320 billable units on day 1 then 160 billable units every 7 days

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- 320 billable units every 7 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ARIXTRA® (FONDAPARINUX)

HCPCS: J1652

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and meets age requirements; **AND**
- Member must have tried and failed the preferred product on the PDL, enoxaparin.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

20 billable units per day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ARRANON® (NELARABINE)

HCPCS: J9261

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age (unless otherwise specified); **AND**
- Member has a diagnosis of T-Cell Acute Lymphoblastic Leukemia or T-Cell Lymphoblastic Lymphoma; **AND**
- Member has not responded to or has relapsed following treatment with at least two chemotherapy regimens

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 50 MG)

225 billable units per 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ASPARLAS® (CALASPARGASE PEGOL-MKNL)

HCPCS: J9118

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is 1 month to 21 years of age; **AND**
- Member must not have a history of serious hypersensitivity reactions with pegylated L-asparaginase therapy; **AND**
- Member must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Member must not have severe hepatic impairment; **AND**
- Used as a component of a multi-agent chemotherapy regimen; **AND**
- Member will receive premedication prior to administration of Asparlas to decrease the risk and severity of both infusion and hypersensitivity reactions (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]); **AND**
- Member has a diagnosis of Acute Lymphoblastic Leukemia.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 UNITS)

750 billable units per 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

AUCATZYL® (OBECABTAGENE AUTOLEUCEL)

HCPCS: Q2058

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have a clinically significant active infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during obecabtagene autoleucel treatment and until immune recovery following treatment; **AND**
- Member will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Member has not received prior CAR-T therapy; **AND**
- Member has not received other anti-CD19 therapy (e.g., blinatumomab,) or member previously received other anti-CD19 therapy and re-biopsy indicates CD19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with obecabtagene autoleucel; **AND**
- Member is at least 18 years of age; **AND**
- Member has a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL); **AND**
  - Member has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Previous therapy has included trial and failure of at least two different tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
  - Member has Philadelphia chromosome (Ph)-negative disease.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit on day 1 and day 10

LENGTH OF AUTHORIZATION

One treatment course (1 split dose infusion), not eligible for renewal

AVTOZMA® (TOCILIZUMAB-ANOH)

HCPCS: Q5156

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Subcutaneous

- 162 billable units every 7 days

Intravenous

- Cytokine Release Syndrome: 3200 billable units
- All other indications: 800 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

BARHEMSYS® (AMISULPRIDE)

HCPCS: J0184

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has post-operative nausea and vomiting; **AND**
- Member has tried and failed therapeutic doses of, or had adverse effects or contraindications to, two different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide); **AND**
- Clinical evidence is provided that preferred antiemetic/antivertigo agents on the PDL will not provide adequate benefit, including what pharmaceutical agents have already been attempted and the outcomes of those trials.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

10 billable units

LENGTH OF AUTHORIZATION

One treatment course (single intravenous injection), not eligible for renewal

BAVENCIO® (AVELUMAB)

HCPCS: J9023

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age, unless otherwise indicated; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (unless tumor upon re-biopsy has demonstrated a change in actionable mutation); **AND**
- Member must meet indication specific criteria below:

Merkel Cell Carcinoma (MCC)

- Member is at least 12 years of age; **AND**
- Used as single-agent therapy; **AND**
  - Member has metastatic disease.

Urothelial Carcinoma (Bladder Cancer)

- Used as single-agent therapy; **AND**
  - Member has locally advanced or metastatic urothelial carcinoma; **AND**
    - Used for disease that progressed during or following platinum-containing chemotherapy; **OR**
  - Used as first-line maintenance treatment; **AND**
    - Member has locally advanced or metastatic urothelial carcinoma (inclusive of bladder, upper GU tract, urethra, and/or prostate cancer); **AND**
    - Member has not progressed with first-line platinum-containing chemotherapy

Renal Cell Carcinoma (RCC)

- Used in combination with axitinib; **AND**
- Used as first-line therapy; **AND**
- Used for the treatment of advanced, relapsed, or stage IV** disease and clear cell histology.

**When used as first line therapy for stage IV disease, disease must be M1 or unresectable T4, M0.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

80 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BELEODAQ® (BELINOSTAT)

HCPCS: J9032

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member does not have severe hepatic impairment defined as total bilirubin > 3 times the upper limit of normal; **AND**
- Member does not have severe renal impairment defined as creatinine clearance (CrCl) < 30 mL/min; **AND**
- Used as a single agent; **AND**
- Member has a diagnosis of Peripheral T-Cell Lymphoma; **AND**
  - Used as subsequent therapy for relapsed or refractory disease; **OR**
  - Used as initial palliative intent therapy

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

1250 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BEOVU® (BROLUCIZUMAB-DBLL)

HCPCS: J0179

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - Diabetic Macular Edema (DME)

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Neovascular age-related macular degeneration

- 12 billable units every 28 days for 3 doses then 12 billable units every 56-84 days

Diabetic Macular Edema

- 12 billable units every 42 days for 5 doses then 12 billable units every 56-84 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

BERINERT® (C1 ESTERASE INHIBITOR, HUMAN)

HCPCS: J0597

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used as monotherapy for treatment of acute hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS(1 BILLABLE UNIT = 10 UNITS)

1000 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

BESPONSA™ (INOTUZUMAB OZOGAMICIN)

HCPCS: J9229

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not previously received treatment with inotuzumab ozogamicin; **AND**
- Member has CD22-positive disease; **AND**
- Baseline electrocardiogram (ECG) is within normal limits prior to initiating therapy and will be periodically monitored during treatment; **AND**
- Member meets indication specific criteria below:

Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

- Member is at least 18 years of age (Note: Adult B-Cell Precursor ALL may be applicable to adolescent and young adult (AYA) members within the age range of 15-39 years); **AND**
  - Member has relapsed or refractory disease; **AND**
    - Used as single agent therapy; **OR**
    - Used in combination with mini-hyperCVD with or without sequential blinatumomab; **AND**
      - Member is Philadelphia chromosome (Ph)-negative; **OR**
      - Member is Philadelphia chromosome (Ph)-positive and refractory to prior tyrosine kinase inhibitor (TKI) therapy; **OR**
    - Used in combination with TKI therapy; **AND**
      - Member is Philadelphia chromosome (Ph)-positive; **OR**
  - Used as frontline therapy; **AND**
    - Used in combination with mini-hyperCVD with sequential blinatumomab as part of consolidation; **AND**
      - Member is Philadelphia chromosome (Ph)-negative

Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

- Member is at least 1 year of age; **AND**
- Member has relapsed or refractory disease; **AND**
  - Used as single agent therapy; **OR**
  - Used in combination with mini-hyperCVD; **AND**
    - Member has BCR::ABL1 negative disease

QUANTITY LIMITS(1 BILLABLE UNIT = 0.1 MG)

63 billable units every 21 days for a maximum of 6 cycles

LENGTH OF AUTHORIZATION

6 months for initial approval, not eligible for renewal

BESREMI® (ROPEGINTERFERON ALFA-2B-NJFT)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Product is being prescribed by or in consultation with a hematologist; **AND**
- Member has a confirmed diagnosis of polycythemia vera; **AND**
- Females of reproductive potential have a negative pregnancy test prior to start date of therapy; **AND**
- Member does not have any FDA labeled contraindications to the requested agent; **AND**
- Member does not have severe renal impairment (i.e., eGFR is < 30 mL/min); **AND**
- Product will not be used in combination with other interferon type products (i.e., alfa-, beta-, gamma-interferon, etc.); **AND**
- Member does not have any of the following conditions:
  - Serious or untreated endocrine disorders associated with an autoimmune disease;
  - Severe or unstable cardiovascular disease, recent stroke, or recent myocardial infarction; **AND**
- Member will have ophthalmological examinations prior to the start of and during therapy; **AND**
- Used as single agent therapy (Note: excludes use when transitioning from hydroxyurea); **AND**
  - Used as cytoreductive treatment; **AND**
    - Member has high-risk disease; **OR**
    - Member has symptomatic low-risk disease; **OR**
    - Member has had an inadequate response, loss of response, or intolerance to at least a 3 month trial of prior cytoreductive therapy; **AND**
      - Member has not previously received treatment with ropeginterferon alfa-2b-njft; **OR**
- Used as a substitute for peginterferon alfa-2a if it is unavailable

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has maintained hematological stability as evidenced by all of the following parameters:
  - Hematocrit less than 45%; **AND**
  - Platelets less than 400 x 10^9/L; **AND**
  - Leukocytes less than 10 x 10^9/L; **AND**
- Member will attempt a dosing interval increase to 4 weeks if they have maintained a complete hematological response or hematological stability after 1 year of treatment at stable doses; **AND**
- Member has an absence of unacceptable toxicity from the drug (e.g., depression, suicidal ideation, severe endocrine toxicities, severe cardiovascular toxicities, severe decreased blood counts, hypersensitivity reactions, pancreatitis, colitis, severe pulmonary toxicity, ophthalmological toxicity, hyperlipidemia, severe hepato- or nephrotoxicity, severe dental/periodontal toxicity, severe dermatologic toxicity).

QUANTITY LIMITS

500 mcg every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BIZENGRI® (ZENOCUTUZUMAB-ZBCO)

HCPCS: J9382

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for 2 months after the last dose; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Member has neuregulin-1 (NRG1) gene fusion positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as single agent therapy; **AND**
- Member meets indication specific criteria below:

Non-Small Cell Lung Cancer (NSCLC)

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as subsequent therapy after disease progression

Pancreatic Adenocarcinoma

- Member has recurrent, advanced, unresectable or metastatic disease; **AND**
- Used as subsequent therapy after disease progression

Biliary Tract Cancers (Intra/Extra-Hepatic Cholangiocarcinoma)

- Member has advanced, unresectable, gross residual (R2), or metastatic disease; **AND**
- Used as subsequent therapy after disease progression

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

750 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BLENREP (BELANTAMAB MAFODOTIN-BLMF)

HCPCS: J9053

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has an ophthalmic exam (including slit lamp exam and BCVA assessment) at baseline, prior to each dose, for new or worsening symptoms, and as clinically indicated; **AND**
- Therapy will be used in combination with preservative-free artificial tears; **AND**
- Member does not have existing corneal epithelial disease (Note: excludes mild punctate keratopathy); **AND**
- Member has not had a prior allogeneic stem cell transplant; **AND**
- Member has a diagnosis of relapsed or refractory Multiple Myeloma; **AND**
  - Used in combination with bortezomib and dexamethasone; **AND**
    - Member has received at least two (2) prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

2800 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BLINCYTO® (BLINATUMOMAB)

HCPCS: J9039

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not received a live vaccine within 2 weeks prior to initiating therapy and will not receive concurrent treatment with lives vaccine while on therapy; **AND**
- Member must meet indication specific criteria below:

Acute Lymphoblastic Leukemia (ALL) – Adult

- Member is at least 18 years of age*; **AND**
- Member has B-cell precursor ALL; **AND**
  - Member has positive minimal residual disease (MRD+) greater than or equal to 0.1%; **AND**
    - Used as a single agent for members in first or second complete remission (CR); **OR**
  - Used as frontline induction therapy; **AND**
    - Used in combination with a tyrosine kinase inhibitor (TKI) for Philadelphia chromosome-positive (Ph+) disease; **OR**
  - Used as part of consolidation therapy; A**ND**
    - Used for Philadelphia chromosome-negative (Ph-) disease; **OR**
    - Used for Ph+ disease; **AND**
      - Used as a single agent as a component of inotuzumab ozogamicin + mini-hyperCVD regimen if refractory to TKIs; **OR**
      - Used in combination with a TKI; **OR**
  - Used as maintenance therapy; **AND**
    - Used as a single agent alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine); **AND**
      - Member has Ph+ disease; **AND**
        - Member is refractory to TKIs; **OR**
      - Member has Ph- disease; **OR**
  - Member has relapsed or refractory disease.

*NCCN recommendations for ALL may be applicable to adolescent and young adult (AYA) patients within the age range of 15-39 years.

Pediatric Acute Lymphoblastic Leukemia (ALL)

- Member is at least 1 month of age*; **AND**
  - Member has infant ALL; **AND**
    - Used in combination with an interfant regimen (e.g., Interfant-06, Interfant-99, etc.) as consolidation therapy; **OR**
  - Member has B-cell precursor ALL; **AND**

- Used for MRD+ ALL as a single agent for first or second complete remission with MRD greater than or equal to 0.1%; **OR**
- Used as part of consolidation therapy; **AND**
  - Used for Ph+ (BCR::ABL1-positive) disease in combination with a TKI (with or without chemotherapy); **OR**
  - Used for Ph- (BCR::ABL1-negative) disease; **OR**
  - Used for Ph-like (BCR::ABL1-like) disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with chemotherapy (Note: may also be used with a TKI or ruxolitinib); **OR**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **AND**
    - Used for Ph- (BCR::ABL1-negative) disease; **OR**
    - Used for Ph+ (BCR::ABL1-positive) disease intolerant/refractory to TKI; **OR**
  - Used as a component of COG AALL1331 regimen; **AND**
    - Used as a single agent for Ph- (BCR::ABL1-negative) disease; **OR**
    - Used in combination with a TKI for Ph+ (BCR::ABL1-positive) disease.

*NCCN recommendations for Pediatric ALL may be applicable to certain adolescent and young adult (AYA) patients up to 30 years of age.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

980 billable units every 42 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BORTEZOMIB (GENERIC VELCADE®)

HCPCS: J9041

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of multiple myeloma; **OR**
- Member has a diagnosis of mantle cell lymphoma; **AND**
  - Used as induction or additional therapy in combination with a rituximab-based regimen; **OR**
  - Used as subsequent therapy as a single agent or in combination with rituximab.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

Multiple Myeloma

- 280 billable units every 35 days

Mantle Cell Lymphoma

- 140 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BOTOX® (ONABOTULINUMTOXINA)

HCPCS: J0585

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member does not have any of the following:
  - Any disorders which may contribute to respiratory or swallowing difficulty
  - Hypersensitivity to any botulinum toxin product
  - Active infection at the proposed injection site; **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**
- Member meets the indication specific criteria below:

Blepharospasms, Strabismus

- Member is at least 12 years of age

Cervical Dystonia

- Member is at least 16 years of age; **AND**
- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck

Spastic Conditions

- Member has one of the following:
  - Upper/Lower Limb spasticity in adults
  - Pediatric upper or lower limb spasticity in members at least 2 years of age

Severe Primary Axillary Hyperhidrosis

- Member has tried and failed at least a 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, sofpironium, etc.); **AND**
  - Member has a history of medical complications such as skin infections or significant functional impairments; **OR**
  - Member has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)

Prophylaxis for Chronic Migraines

- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**

- Member is utilizing prophylactic intervention modalities (i.e., avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, physical therapy, etc.); **AND**
- Other causes of headaches have been ruled out; **AND**
- Member has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months; **AND**
- On at least 8 days per month for at least 3 months, headaches have characteristics and symptoms consistent with migraine; **AND**
- Member has tried and failed at least a two month trial of two preferred agents for migraine prophylaxis listed on the PDL (e.g., Quilipta, Nurtec ODT, Aimovig, Ajovy, Emgality)

Incontinence due to Detrusor Overactivity

- Member is at least 5 years of age; **AND**
- Member does not have a current, untreated urinary tract infection; **AND**
- Member has detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing; **AND**
- Member has failed a 1 month or longer trial of two medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

Overactive Bladder

- Member does not have a current, untreated urinary tract infection; **AND**
- Member has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Member has failed a 1 month or longer trial of two medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 UNIT)

Strabismus, Overactive Bladder

- 100 billable units every 84 days

Blepharospasm, Chronic Migraine, Detrusor Overactivity

- 200 billable units every 84 days

Cervical Dystonia

- 300 billable units every 84 days

Upper and Lower Limb Spasticity

- 400 billable units every 84 days

Severe Primary Axillary Hyperhidrosis

- 100 billable units every 112 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

BREYANZI® (LISOCABTAGENE MARALEUCEL)

HCPCS: Q2054

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during lisocabtagene maraleucel treatment and until immune recovery following treatment; **AND**
- Member will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Member has not received prior CAR-T therapy; **AND**
- Member has not received other anti-CD19 therapy (e.g., tafasitamab, blinatumomab, loncastuximab tesirine) or member previously received other anti-CD19 therapy and rebiopsy indicates CD19 positive disease or member has residual tumor activity; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**
- Member does not have primary central nervous system lymphoma; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with lisocabtagene maraleucel; **AND**
- Member meets indication specific criteria below:

B-Cell Lymphomas

- Member has diffuse large B cell lymphoma (DLBCL), high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma (FL) grade 3b, **AND**
  - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease within 12 months after completion of first-line therapy; **OR**
  - Used for relapsed or refractory disease after first-line chemoimmunotherapy in members not eligible for hematopoietic stem cell transplantation (HSCT) **OR**
  - Used as second-line therapy for relapsed disease > 12 months after completion of first-line therapy if no intention to proceed to transplant; **OR**
  - Used as additional therapy for relapsed disease > 12 months after completion of first-line therapy and a partial response following second-line therapy; **OR**
  - Used for relapsed or refractory disease after two (2) or more lines of systemic therapy; **OR**
- Member has Follicular Lymphoma Grade 1, 2, or 3a; **AND**
  - Member has relapsed or refractory disease; **AND**
  - Member has received at least two (2) prior lines of therapy; **OR**

- Member has Mantle Cell Lymphoma; **AND**
  - Member has relapsed or refractory disease; **AND**
  - Used as subsequent therapy after prior covalent Bruton Tyrosine Kinase Inhibitor (BTKi) therapy (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib); **AND**
    - Member had no response or progressive disease following second-line therapy with covalent BTKi or other continuous treatment regimens (i.e., lenalidomide and rituximab); **OR**
    - Member had partial response, no response, or progressive disease following second-line therapy with fixed-duration regimens; **OR**
    - Member has relapsed or progressive disease that is in second or greater relapse; **OR**
- Member has Marginal Zone Lymphoma; **AND**
  - Member has relapsed or refractory disease; **AND**
  - Member has received at least two (2) prior lines of systemic therapy.

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (CLL/SLL)

- Used for relapsed or refractory disease; **AND**
- Member has received at least **two** prior lines of therapy including a Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib, etc.) and a B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 infusion of up to 110 million autologous anti-CD19 CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

BRINEURA® (CERLIPONASE ALFA)

HCPCS: J0567

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 37 weeks post-menstrual age (gestational age at birth plus post-natal age) and weighs at least 2.5 kg; **AND**
- Member must not have any acute intraventricular access device-related complications (e.g., leakage, extravasation of fluid, or device failure); **AND**
- Member must not have ventriculoperitoneal shunts; **AND**
- Member has no signs or symptoms of acute, unresolved localized infection on or around the device insertion site (e.g., cellulitis or abscess); or a suspected or confirmed CNS infection (e.g., cloudy CSF, positive CSF gram stain, or meningitis); **AND**
- Member must have a definitive diagnosis of late infantile CLN2 confirmed by deficiency of the lysosomal enzyme tripeptidyl peptidase-1 (TPP1) and/or molecular analysis indicating two (2) pathogenic variants/mutations in the TPP1/CLN2 gene on chromosome 11p15; **AND**
- Member is ambulatory; **AND**
- Members with a history of bradycardia, conduction disorder, or with structural heart disease will have electrocardiogram (ECG) monitoring performed during each infusion.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug or complications from the device; **AND**
- Member has had a 12-lead ECG evaluation performed within the last 6 months; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units (1 kit containing 2 vials) every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

BRIUMVI® (UBLITUXIMAB-XIIY)

HCPCS: J2329

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been screened for Hepatitis B (HBV) prior to initiating treatment and does not have active disease (i.e., positive HBsAg and anti-HBV tests); **AND**
- Member has a baseline assessment of serum immunoglobulin; **AND**
- Member will not receive live or live attenuated vaccines while on therapy or within 4 weeks prior to the initiation of treatment; **AND**
- Member is immunocompetent and free of an active infection; **AND**
- Briumvi will be used as single therapy; **AND**
- Member has not received a dose of ocrelizumab or ublituximab within the past 5 months; **AND**
- Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
- Member has a diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS*], active secondary progressive disease [SPMS**], or clinically isolated syndrome [CIS***]); **AND**
- Member has a documented trial and failure of **two** of the preferred Multiple Sclerosis agents (see Multiple Sclerosis on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- **Initial dose:** 150 billable units on day 1 and 450 billable units on day 15 and 168
- **Subsequent doses:** 450 billable units every 168 days thereafter

Definitions

***Definitive diagnosis of MS with a relapsing-remitting course is based upon:**

- Dissemination in space (see below) AND one or more of the following:
  - Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  - Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  - Dissemination in time (DIT) (see below)
  - Presence of lesions in at least four of five CNS anatomical locations; **OR**

- Lesions present in one CNS site (including members with 12 months or longer progression from onset) AND one or more of the following:
  - CSF positivity and CVS positivity
  - CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  - DIT (see below) and CVS positivity
  - DIT (see below) and PRL positivity

Unless contraindicated, MRI should be obtained (even if criteria are met).

Dissemination in time (development/appearance of new CNS lesions over time)

- ≥ 2 clinical attacks; **OR**
- Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR**
- A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI.

Dissemination in space (development of lesions in distinct anatomical locations within the CNS; multifocal)

- MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR**
- In members with progressive disease (members with 12 months or longer progression from onset), two spinal cord lesions

****Active Secondary Progressive MS (SPMS) is defined as the following:**

- Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND**
- Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in members with EDSS ≤ 5.5 or increase by 0.5 in members with EDSS ≥ 6); **AND**
  - At least 1 relapse within the previous 2 years; **OR**
  - Member has gadolinium-enhancing activity **OR** new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI.

*****Definitive diagnosis of CIS is based upon ALL of the following:**

- A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
- Neurologic symptom duration of at least 24 hours, with or without recovery
- Absence of fever or infection
- Member is not known to have multiple sclerosis

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

CARVYKTI® (CILTACABTAGENE AUTOLEUCEL)

HCPCS: Q2056

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received prior CAR-T therapy; **AND**
- Member does not have an active infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during ciltacabtagene autoleucel treatment, and until immune recovery following treatment; **AND**
- Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Member does not have known central nervous system (CNS) involvement with myeloma; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with ciltacabtagene autoleucel; **AND**

Multiple Myeloma

- Member has relapsed or refractory disease; **AND**
  - Member has received at least one (1) prior line of therapy, including a proteasome inhibitor (e.g., bortezomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, thalidomide); **AND**
  - Member is refractory to lenalidomide.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 dose of up to 100 million autologous CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

CASGEVY® (EXAGAMGLOGENE AUTOTEMCEL)

HCPCS: J3392

CRITERIA FOR APPROVAL

Beta Thalassemia

Coverage is provided under the following conditions:

- Member is at least ~~12~~ 2 years of age; **AND**
- Member has a documented diagnosis of homozygous beta thalassemia or compound heterozygous beta thalassemia including β-thalassemia/hemoglobin E (HbE) as outlined by the following:
  - Member diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
  - Member has severe microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A (HbA) and increased HbA2 with or without increased amounts of hemoglobin F (HbF); **AND**
- Member has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year or ≥ 10 units/year of packed red blood cells (pRBCs) in the two years preceding therapy; **AND**
- Member will be transfused prior to apheresis to a total Hb ≥ 11 g/dL for 60 days prior to myeloablative conditioning; **AND**
- Member does not have any of the following:
  - Severely elevated iron in the heart (i.e., members with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction [LVEF] < 45% by echocardiogram); **OR**
  - Advanced liver disease (i.e., AST or ALT > 3 times the upper limit of normal [ULN], or direct bilirubin value > 2.5 times the ULN, or if a liver biopsy demonstrated bridging fibrosis or cirrhosis)

Sickle Cell Disease

Coverage is provided under the following conditions:

- Member is at least ~~12~~ 2 years of age; **AND**
- Member has had either genetic testing or hemoglobin fractionation to confirm a diagnosis of sickle cell disease; **AND**
- Member has history of use or intolerance to hydroxyurea (per healthcare professional judgement) at any point in the past; **AND**
- Member is clinically stable and fit for transplantation; **AND**
- CGT Product is prescribed in consultation with a board-certified hematologist with SCD (sickle cell disease) expertise; **AND**
- Member has experienced recurrent VOCs (vaso-occlusive crisis) (defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

- A single dose of Casgevy containing a minimum of 3.0×10^6 CD34+ cells/kg of body weight, in multiple vials

Requests for subsequent use of exagamglogene after receipt of other gene therapies (e.g., lovotibeglogene, betibeglogene) will be evaluated on a case-by-case basis.

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

CEREZYME® (IMIGLUCERASE)

HCPCS: J1786

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Used as a single agent; **AND**
- Member has a documented diagnosis of Type 1 or Type 3 Gaucher Disease confirmed by one of the following:
  - Significantly reduced or absent glucocerebrosidase enzyme activity as measured by a beta-glucosidase leukocyte (BGL) test
  - Detection of mutations in the glucocerebrosidase (GBA) gene; **AND**
- Member has non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease defined as one or more of the following:
  - Anemia-related symptoms [i.e., blood transfusion dependency and/or hemoglobin ≤ 11 g/dL (women and children) or ≤ 12 g/dL (men)]
  - Thrombocytopenia (platelet count ≤ 120,000/mm3)
  - Hepatomegaly or splenomegaly
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.)
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, abdominal distension, diminished quality of life, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 UNITS)

720 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

CIMZIA® (CERTOLIZUMAB PEGOL)

HCPCS: J0717

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Plaque Psoriasis

- 400 billable units every other week

Polyarticular Juvenile Idiopathic Arthritis

- 400 billable units on weeks 0, 2, and 4, then 200 billable units every other week

All other indications

- 400 billable units on weeks 0, 2, and 4, then 400 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

CINQAIR® (RESLIZUMAB)

HCPCS: J2786

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Member has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 400 cells/µL; **AND**
- Cinqair will not be coadministered with another monoclonal antibody (e.g., omalizumab, mepolizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Cinqair will be used as add-on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1); **AND**
- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- 400 billable units every 4 weeks

Definitions

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

CINRYZE® (C1 ESTERASE INHIBITOR, HUMAN)

HCPCS: J0598

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used for prophylaxis of hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 IU)

2000 billable units every 30 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

CINVANTI® (APREPITANT)

HCPCS: J0185

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

520 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

COLUMVI® (GLOFITAMAB-GXBM)

HCPCS: J9286

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Prophylaxis for infection will be followed according to local guidelines (e.g., Pneumocystis jirovecii pneumonia (PJP), Herpes virus, cytomegalovirus, etc.); **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member does not have primary central nervous system (CNS) lymphoma or CNS involvement of disease; **AND**
- Member has not received prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Member will receive tumor lysis syndrome prophylaxis during therapy (e.g., anti-hyperuricemics and adequate hydration); **AND**
- Member is not refractory to obinutuzumab treatment and will be pretreated with obinutuzumab prior to treatment with glofitamab; **AND**
  - Used as a single agent and after at least two prior lines of systemic therapy; **AND**
    - Member has diffuse large B-cell Lymphoma (DLBCL) (including DLBCL, not otherwise specified), high-grade B-cell lymphoma, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
      - Used for partial response, progressive, relapsed, or refractory disease; **OR**
    - Member has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**
      - Used for partial response, no response, progressive, relapsed, or refractory disease; **OR**
  - Used in combination with GemOx (gemcitabine and oxaliplatin) as subsequent therapy; **AND**
    - Member has diffuse large B-cell Lymphoma (DLBCL), high-grade B-cell lymphomas, or HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL not otherwise specified, or HIV-related plasmablastic lymphoma); **AND**
      - Used for primary refractory disease or relapsed disease <12 months after completion of first-line therapy AND member is a non-candidate for CAR T-cell therapy; **OR**
      - Used for relapsed disease >12 months after completion of first-line therapy AND no intention to proceed to transplant; **OR**
      - Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
    - Member has post-transplant lymphoproliferative disorder (PTLD); **AND**
      - Used for primary refractory disease or relapsed disease <12 months after completion of initial treatment with chemoimmunotherapy AND member is a non-candidate for CAR T-cell therapy; **OR**

- Used for relapsed disease >12 months after completion of initial treatment with chemoimmunotherapy AND no intention to proceed to transplant; **OR**
- Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2.5 MG)

12 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal up to a total of twelve 21-day treatment cycles

COSELA® (TRILACICLIB)

HCPCS: J1448

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Will not be used concomitantly with colony stimulating factors for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy; **AND**
- Member has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND**
- Used as prophylactic therapy to decrease the incidence of chemotherapy-induced myelosuppression; **AND**
- Member is undergoing myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) or etoposide-containing regimen; **OR**
  - Topotecan-containing regimen.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

3000 billable units every 21 days

LENGTH OF AUTHORIZATION

4 months for initial approval, 4 months for renewal

COSENTYX® (SECUKINUMAB)

HCPCS: J3247

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

750 billable units

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

CRYSVITA® (BUROSUMAB-TWZA)

HCPCS: J0584

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy; **AND**
- Member has a baseline fasting serum phosphorus level showing current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range; **AND**
- Member has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); **AND**
- Other causes of hypophosphatemia (e.g., autosomal dominant or recessive hypophosphatemic rickets) have been ruled out; **AND**
- Must be prescribed by, or in consultation with, a nephrologist or endocrinologist; **AND**
- Will not be used concomitantly with oral phosphate and/or active vitamin D analogs; **AND**
- Member does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of < 30 mL/min; **AND**
- Member 25-hydroxy vitamin D levels will be monitored at baseline and intermittently and member will be supplemented with cholecalciferol or ergocalciferol to maintain levels in the normal range for age; **AND**
- Member meets indication specific criteria below:

X-linked Hypophosphatemia

- Member is at least 6 months of age; **AND**
- Diagnosis is confirmed by identifying at least one of the following:
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL (> 230 RU/mL in children 3 months-17 years; > 180 RU/mL in adults using EDTA plasma); **OR**
  - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEXgene) mutations in the member; **AND**
- Adult members must have had an inadequate response from oral phosphate and active vitamin D analogs

Tumor-induced Osteomalacia

- Member is at least 2 years of age; **AND**
- Must have a diagnosis of tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized; **AND**
- Diagnosis is confirmed by identifying excessive serum FGF23 (i.e., level ≥ 100 pg/mL) that is not amenable to cure by surgical excision of the offending tumor/lesion.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**

- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

X-linked Hypophosphatemia

- 90 billable units every 14 days

Tumor-Induced Osteomalacia

- 180 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

CYRAMZA® (RAMUCIRUMAB)

HCPCS: J9308

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have uncontrolled severe hypertension; **AND**
- Member must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Member must meet indication specific criteria below:

Colorectal Cancer (CRC)

- Used in combination with irinotecan or FOLFIRI (irinotecan, folinic acid/leucovorin, and fluorouracil); **AND**
- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
  - Member has not previously been treated with irinotecan-based therapy.

Gastric, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancers

- Member has adenocarcinoma histology; **AND**
- Used as subsequent therapy; **AND**
- Used as a single agent OR in combination with paclitaxel OR in combination with an irinotecan-based regimen; **AND**
  - Member has advanced, recurrent, or metastatic disease; **OR**
  - Member is not a surgical candidate.

Hepatocellular Carcinoma (HCC)

- Used as a single agent; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Member has an alfa-fetoprotein (AFP) level of ≥ 400 ng/mL; **AND**
- Member has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments).

Non-Small Cell Lung Cancer (NSCLC)

- Member has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used in combination with docetaxel; **AND**
    - Used as subsequent therapy for first progression after initial systemic therapy; **AND**
    - Member has not previously been treated with docetaxel or ramucirumab; **OR**
  - Used in combination with erlotinib; **AND**
    - Member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test; **AND**

- Used as first-line therapy; **OR**
- Used for continuation of therapy following disease progression on combination erlotinib and ramucirumab therapy for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; **AND**
  - Member has T790M negative disease.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…); **OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

240 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

DANYELZA® (NAXITAMAB-GQGK)

HCPCS: J9348

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Will not be used in combination with other GD2-binding monoclonal antibodies; **AND**
- Member does not have uncontrolled hypertension; **AND**
- Member has a diagnosis of High-Risk Neuroblastoma; **AND**
- Used in combination with temozolomide, irinotecan, and sargramostim; **AND**
  - Used following induction; **AND**
    - Member has minor response or stable disease; **AND**
      - Used as bridging therapy to standard consolidation; **OR**
    - Member has progressive disease; **OR**
  - Used following consolidation for progressive disease; **OR**
- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
  - Member has relapsed or refractory disease in the bone or bone marrow; **AND**
  - Member had at least a partial or minor response or stable disease to at least one prior systemic therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

960 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

DARZALEX® (DARATUMUMAB)

HCPCS: J9145

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies; **AND**
- Member has a diagnosis of Multiple Myeloma; **AND**
- Used in the treatment of newly diagnosed disease in members who are ineligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Lenalidomide and dexamethasone; **OR**
  - Bortezomib, melphalan, and prednisone; **OR**
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in members who are eligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
  - Bortezomib, thalidomide, and dexamethasone (VTd); **OR**
  - Carfilzomib, lenalidomide, and dexamethasone; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and ONE of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
- Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.); **OR**
- Used as single agent therapy; **AND**
  - Member received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); **OR**
  - Member is double refractory to a proteasome inhibitor and an immunomodulatory agent.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…); **OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

180 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

DARZALEX FASPRO® (DARATUMUMAB AND HYALURONIDASE-FIHJ)

HCPCS: J9144

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies; **AND**
- Member meets indication specific criteria below:

Multiple Myeloma

- Used in the treatment of newly diagnosed disease in members who are ineligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Lenalidomide and dexamethasone; **OR**
  - Bortezomib, melphalan, and prednisone; **OR**
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in members who are eligible for autologous stem cell transplant (ASCT) in combination with ONE of the following regimens:
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
  - Bortezomib, thalidomide, and dexamethasone (VTd); **OR**
- Used as subsequent therapy for relapsed or refractory/progressive disease in combination with dexamethasone and ONE of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
- Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (bortezomib, carfilzomib, etc.); **OR**
- Used as single agent therapy; **AND**
  - Member received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.); **OR**
  - Member is double refractory to a proteasome inhibitor and an immunomodulatory agent; **OR**
  - Member has high-risk smoldering myeloma.

Systemic Light Chain Amyloidosis

- Member must NOT have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease; **AND**
  - Used for newly diagnosed disease OR as a repeat of initial therapy if relapse-free for several years; **AND**
    - Used in combination with bortezomib, cyclophosphamide, and dexamethasone (D-VCd).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

180 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

DATROWAY® (DATOPOTAMAB DERUXTECAN-DLNK)

HCPCS: J9011

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a history of interstitial lung disease (ILD)/pneumonitis requiring treatment with steroids or the presence of ongoing symptomatic ILD/pneumonitis; **AND**
- Member does not have the presence of clinically significant corneal disease; **AND**
- Member does not have active untreated brain metastases; **AND**
- Member will have an ophthalmic exam including visual acuity testing, slit lamp examination (with fluorescein staining), intraocular pressure, and fundoscopy best corrected visual acuity (BCVA) conducted at baseline and periodically during treatment; **AND**
- Member has not previously received or will not be used concomitantly with other TROP2- (i.e., sacituzumab govitecan, etc.) or topoisomerase-I- (i.e., topotecan, irinotecan, etc.) targeted therapies; **AND**
- Used as a single agent; **AND**
- Member meets indication specific criteria below:

Breast Cancer

- Member has human epidermal growth factor receptor 2 (HER2)-negative, hormone receptor (HR)-positive disease; **AND**
  - Member has unresectable or metastatic disease; **AND**
  - Member has received prior endocrine-based therapy; **AND**
  - Member has been treated with chemotherapy in the unresectable or metastatic disease setting; **OR**
- Member has unresectable or metastatic triple-negative disease; **AND**
  - Member is not a candidate for PD-1/PD-L1 inhibitor therapy

Non-Small Cell Lung Cancer (NSCLC)

- Member has EGFR-mutated disease as detected by an FDA-approved or CLIA compliant test; **AND**
- Member has locally advanced or metastatic disease; **AND**
- Member has received prior EGFR-directed therapy and platinum-based chemotherapy

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

600 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

DAXXIFY® (DAXIBOTULINUMTOXINA)

HCPCS: J0589

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have any of the following:
  - Any disorders which may contribute to respiratory or swallowing difficulty
  - Hypersensitivity to any botulinum toxin product
  - Active infection at the proposed injection site; **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**
- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 UNIT)

300 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

DENOSUMAB

HCPCS: J0897, Q5136, Q5157, Q5158, Q5159, Q5161, Q5162, Q5165, Q5166, Q5167, Q5171

Preferred products are listed under RANK Ligand Inhibitors on the PDL

CRITERIA FOR APPROVAL

Initial requests of Prolia, Bildyos, Bosaya, Conexxence/denosumab-bnht, Enoby, Jubbonti, Ospomyv/denosumab-dssb, Stoboclo/denosumab-bmwo or other densoumab products with bioequivalence to Prolia:

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Member does not have hypocalcemia; **AND**
- There has been confirmation that the member is not pregnant; **AND**
- Provider attests that the requested product will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Request is for a preferred product on the PDL (see RANK Ligand Inhibitors on the PDL); **OR**
  - Member has had a therapeutic failure of the preferred Prolia bioequivalent; **AND**
- Member meets indication specific criteria below:

Osteoporosis

- For biological females, the member must be post-menopausal; **AND**
- Member is at high risk of fracture**; **AND**
- Member has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - T-score by DXA of ≤ -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **OR**
  - History of fragility fracture to the hip or spine, regardless of T-score; **OR**
  - T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **AND**
    - History of fracture of proximal humerus, pelvis, or distal forearm; **OR**
    - FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Member has had a 12 month trial and failure or intolerance* to previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid.

Glucocorticoid-Induced Osteoporosis

- Member is initiating or continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 2.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 3 months; **AND**
- Member is at increased risk of fracture***; **AND**
- Member has had a 12 month trial and failure or intolerance* to previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid.

Osteoporosis Treatment and Prevention in Prostate Cancer

- Member is receiving androgen deprivation therapy; **AND**
- Member is at high risk of fracture**.

Osteoporosis Treatment and Prevention in Breast Cancer

- Member is receiving adjuvant aromatase inhibitor therapy for breast cancer; **AND**
- Member is at high risk of fracture**.

Initial requests of Xgeva, Aukelso, Bilprevda, Bomyntra/denosumab-bnht, Osenvelt/denosumab-bmwo, Wyost, Xbryk, Xtrenbo, or other densoumab products with bioequivalence to Xgeva:

Coverage is provided under the following conditions:

- Member will receive calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Member does not have hypocalcemia; **AND**
- Provider attests that the requested product will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Request is for a preferred product on the PDL (see RANK Ligand Inhibitors on the PDL); **OR**
  - Member has had a therapeutic failure of the preferred Xgeva bioequivalent; **AND**
- Member meets indication specific criteria below:

Prevention of Skeletal-Related Events in Members with Multiple Myeloma or Bone Metastases from Solid Tumors

- Member is at least 18 years of age; **AND**
  - Member has had an inadequate response, contraindication* or intolerance to at least a 3 month trial of zoledronic acid; **OR**
  - Member has metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC).

Giant Cell Tumor of the Bone

- Member is at least 12 years of age and skeletally mature; **AND**
- Disease is unresectable or surgical resection is likely to result in severe morbidity.

Hypercalcemia of Malignancy

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of cancer; **AND**
  - Member has a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven (7) day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid; **OR**
  - Member has a documented contraindication**** or intolerance to intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**

- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Prolia and bioequivalent products

- 60 billable units every 6 months

Xgeva and bioequivalent products

- 120 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

Denosumab products include: Prolia®, Bildyos®, Bosaya®, Conexxence®/denosumab-bnht, Enoby™, Jubbonti®, Ospomyv™/denosumab-dssb, Stoboclo®/denosumab-bmwo, Xgeva®, Aukelso™, Bilprevda®, Bomyntra®/denosumab-bnht, Osenvelt®/denosumab-bmwo, Wyost®, Xbryk, Xtrenbo™ or other products with bioequivalence to Prolia® and Xgeva®.

***Failed clinical trial is defined as one or more of the following**:

- Decrease in T-score in comparison with baseline T-score from DXA scan
- Member has a new fracture while on bisphosphonate therapy

***Examples of contraindications to oral bisphosphonate therapy include the following**:

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus
- Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass)
- Documented pre-existing hypocalcemia
- Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min

****High risk for fractures include, but are not limited to, one or more of the following:**

- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for >3 months (ever)

*****Increased risk for glucocorticoid-induced osteoporosis fracture include, but are not limited to, one or more of the following:**

- Prior osteoporotic fracture
- High-dose glucocorticoid use (i.e., prednisone [or equivalent] ≥30 mg/d >30 d or ≥5 g/year)
- FRAX glucocorticoid adjusted 10-year risk of major osteoporotic fracture ≥20% or hip ≥3%
- T-score by DXA of <-2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site

**** **Examples of contraindications to injectable bisphosphonate therapy include the following:**

- Documented pre-existing hypocalcemia
- Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min

DEXTENZA® (DEXAMETHASONE INSERT)

HCPCS: J1096

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is free of ocular or periocular infections (including active epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella, mycobacterial infections, fungal diseases, and dacryocystitis, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Member meets indication specific criteria below:

Ocular Inflammation and Pain Following Ophthalmic Surgery

- Approvable if member meets universal criteria above.

Itching Associated with Allergic Conjunctivitis

- Member is at least 2 years of age; **AND**
- Will not be used in pediatric members that require sedation for the insertion procedure; **AND**
- Member avoids or reduces contact with known allergens; **AND**
- Member has experienced intolerable side effects or lack of therapeutic response from one of the following topical therapies:
  - Mast cell stabilizers (e.g., cromolyn, nedocromil, lodoxamide, etc.)
  - Antihistamines (e.g., azelastine, olopatadine, ketotifen, epinastine, bepotastine, alcaftadine, etc.)
  - Vasoconstrictors (e.g., naphazoline, etc.)
  - NSAIDs (e.g., ketorolac tromethamine); **AND**
- Member has had a lack of therapeutic response from short-term topical corticosteroids.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

8 billable units every 1 month

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

DYSPORT® (ABOBOTULINUMTOXINA)

HCPCS: J0586

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member does not have any of the following:
  - Any disorders which may contribute to respiratory or swallowing difficulty
  - Hypersensitivity to any botulinum toxin product
  - Hypersensitivity to cow's milk protein
  - Active infection at the proposed injection site; **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**
- Member meets the indication specific criteria below:

Cervical Dystonia

- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck.

Spastic Conditions

- Member has one of the following:
  - Upper/Lower Limb spasticity in adults
  - Pediatric upper or lower limb spasticity in members at least 2 years of age.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 UNITS)

300 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ELAHERE® (MIRVETUXIMAB SORAVTANSINE-GYNX)

HCPCS: J9063

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member at least 18 years of age; **AND**
- Therapy will be used in combination with artificial tears and ophthalmic topical steroids; **AND**
- Member has a baseline ophthalmological test (i.e., visual acuity and slit lamp exam) obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (i.e., every other cycle for the first 8 cycles, and as clinically indicated); **AND**
- Member does not have moderate to severe hepatic impairment (total bilirubin >1.5 ULN); **AND**
- Member does not have any of the following:
  - Non-infectious interstitial lung disease or pneumonitis (Grade 3 or 4); **AND**
  - Peripheral neuropathy greater than Grade 1; **AND**
  - Active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/monitoring (e.g., uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, macular degeneration, presence of papilledema, and/or monocular vision); **AND**
- Member has folate receptor alpha (FRα) expression positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Member has persistent, recurrent, progressive or relapsed disease; **AND**
  - Member has low-grade serous carcinoma; **AND**
    - Member has platinum-resistant disease; **AND**
      - Used as a single agent or in combination with bevacizumab; **OR**
    - Member has platinum-sensitive disease; **AND**
      - Used as a single agent; **OR**
  - Member has epithelial ovarian/fallopian tube/primary peritoneal cancer, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma of the ovary, mucinous neoplasms of the ovary, or grade 1 endometrioid carcinoma; **AND**
    - Member is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
      - Member has platinum-resistant disease; **AND**
        - Used as a single agent or in combination with bevacizumab; **OR**
      - Member has platinum-sensitive disease treated with two prior lines of platinum-based therapy; **AND**
        - Used as a single agent.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**

- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

700 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ELAPRASE® (IDURSULFASE)

HCPCS: J1743

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 16 months of age; **AND**
- Documented baseline age-appropriate values for one or more of the following have been obtained:
  - Members 5 years of age or greater: 6-minute walk test (6MWT), percent predicted forced vital capacity (FVC), joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ), and/or urinary glycosaminoglycan (uGAG); **OR**
  - Members 16 months to less than 5 years of age: spleen volume, liver volume, FVC, 6-MWT, and/or urinary glycosaminoglycan (uGAG); **AND**
- Therapy is being used to treat non-central nervous system manifestations of the disease and member does not have severe, irreversible cognitive impairment (Requests for continued therapy in members with severe, irreversible cognitive impairment will be reviewed on a case-by case basis); **AND**
- Member has a definitive diagnosis of Mucopolysaccharidosis II (MPS II) as confirmed by one of the following:
  - Deficient or absent iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; **OR**
  - Detection of pathogenic mutations in the IDS gene by molecular genetic testing.

NOTE: For very young patients in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

240 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ELELYSO® (TALIGLUCERASE ALFA)

HCPCS: J3060

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 4 years of age; **AND**
- Member has a confirmed diagnosis of Type 1 Gaucher Disease and is using this medication for long-term enzyme replacement therapy.

RENEWAL CRITERIA

- Member continues to meet initial approval criteria defined above; **AND**
- There is absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions and anaphylaxis; **AND**
- Disease response with treatment as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in anemia-related symptoms (i.e., improvement in hemoglobin and/or decrease in blood transfusion dependency)
  - Improvement in platelet counts
  - Reduction in size of liver or spleen
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, abdominal distension, quality of life).

QUANTITY LIMITS (1 BILLABLE UNIT = 10 UNITS)

700 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL)

HCPCS: J1413

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is ambulatory; **AND**
- Member age is at least 4 years of age; **AND**
- Member is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.); **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Elevidys will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); **AND**
- Member troponin-I levels will be monitored at baseline and subsequently as clinically indicated; **AND**
- Member will have baseline liver function assessed prior to and following therapy for at least 3 months and as indicated; **AND**
- Member must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by ELISA (**Note**: An FDA authorized test for the detection of AAVrh74 total binding antibodies is not currently available. Currently available tests may vary in accuracy and design.); **AND**
- Member does **not** have any deletion in exon 8 and/or exon 9 in the DMD gene.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 therapeutic dose (up to 70 vials [700 mL] based on weight)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ)

HCPCS: J2508

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Must not be used in combination with migalastat or agalsidase beta; **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Deficiency in α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells (males only); **OR**
  - Detection of pathogenic mutations in the GLA gene by molecular genetic testing; **AND**
- Member has a baseline value for at least one of the following:
  - Tissue globotriaosylceramide (Gb3/GL-3) inclusions
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3)
  - Clinical signs and/or symptoms of disease (e.g., dermatologic, gastrointestinal, pulmonary, vascular, renal, cardiac, neurologic manifestations).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

115 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ELITEK® (RASBURICASE)

HCPCS: J2783

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 month of age; **AND**
- Member must not have a deficiency in glucose-6-phosphate dehydrogenase (G6PD); **AND**
- Member must be receiving chemotherapy for leukemia, lymphoma, or solid tumors; **AND**
  - Used as prophylactic therapy in members whose chemotherapy is expected to result in tumor lysis and subsequent elevation of plasma uric acid; **AND**
    - Member must be at high-risk for developing hyperuricemia; **OR**
  - Used for treatment in members who develop hyperuricemia despite standard prophylactic therapies (i.e., hydration, allopurinol, febuxostat, etc.).

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

45 billable units daily for 5 days; one 5-day therapy course only

LENGTH OF AUTHORIZATION

One treatment course consisting of 5 days of therapy, not eligible for renewal

ELREXFIO™ (ELRANATAMAB-BCMM)

HCPCS: J1323

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of step-up dose 1 and step-up dose 2; **AND**
- Member had an absence of unacceptable toxicity while on inpatient administration of step-up doses; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection according to local guidelines; **AND**
- Member has not had an allogenic or an autologous stem cell transplant within the previous 12 weeks; **AND**
- Used as single agent treatment; **AND**
- Member has a diagnosis of relapsed or refractory multiple myeloma; **AND**
- Member has received at least 4 prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

76 billable units weekly through week 24, then 76 billable units every two weeks thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ELZONRIS® (TAGRAXOFUSP-ERZS)

HCPCS: J9269

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age; **AND**
- Member has CD123-positive/expressing disease; **AND**
- Used as single agent therapy; **AND**
- Member has a serum albumin level of at least 3.2 g/dL prior to initiating therapy and will be monitored subsequently throughout therapy; **AND**
- Member does not have significant cardiovascular disease (e.g., uncontrolled or any NYHA Class 3 or 4 congestive heart failure, uncontrolled angina, history of myocardial infarction or stroke within 6 months of initiating therapy, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication, baseline left ventricular ejection fraction below the institutional lower limit of normal); **AND**
- Member does not have active or suspected CNS leukemia; **AND**
- Member must have a definitive diagnosis of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites; **AND**
  - Used as induction therapy in members who are candidates for intensive remission therapy; **OR**
  - Used as treatment until progression if a complete response (CR) was achieved after induction; **OR**
  - Used as treatment for relapsed/refractory disease if not already used.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MCG)

1000 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

EMPLICITI® (ELOTUZUMAB)

HCPCS: J9176

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has previously treated relapsed or progressive multiple myeloma; **AND**
  - Used in combination with lenalidomide and dexamethasone; **OR**
  - Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1200 billable units every 7 days for 8 doses, (or 1200 billable units on days 1 and 11 of each 21 day cycle for 12 doses), then 2400 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

EMRELIS™ (TELISOTUZUMAB VEDOTIN-TLLV)

HCPCS: J9326

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; AND
- Member has a diagnosis of locally advanced or metastatic non-squamous non-small cell lung cancer; **AND**
- Member has received a prior systemic therapy; **AND**
- Member has high c-Met protein overexpression [greater than or equal to 50% of tumor cells with strong (3+) staining], as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test; **AND**
- Member is epidermal growth factor receptor (EGFR) mutation negative (wild-type); **AND**
- Member will be monitored for all of the following signs and symptoms:
  - Ocular surface disorders during treatment and will receive an ophthalmic examination (and treatment, if required) for Grade 2 or greater ocular toxicity; **AND**
  - Interstitial lung disease and/or pneumonitis; **AND**
  - New or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness; **AND**
  - Severe infusion related reactions; **AND**
- Used as single agent therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

200 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY)

HCPCS: J3403

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections; **AND**
- Member does not have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM); **AND**
- Member will be monitored for signs and symptoms of vision loss (e.g., BCVA, etc.) and infectious endophthalmitis at baseline and periodically during treatment; **AND**
- Member will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity); **AND**
- Member does not have evidence of other ocular disease that would preclude treatment of MacTel; **AND**
- Member will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery; **AND**
- Member has not received intravitreal steroid therapy or intravitreal anti–vascular endothelial growth factor (VEGF) therapy, for non-neovascular MacTel within the last 3 months; **AND**
- Member has a diagnosis of macular telangiectasia, type 2, in at least one eye, as evidenced by typical fluorescein leakage and at least one (1) other of the following features of disease:
  - Hyperpigmentation outside a 500-micron radius from the center of the fovea
  - Retinal opacification
  - Crystalline deposits
  - Right angle vessels
  - Inner/outer lamellar cavities; **AND**
- Member does **not** have neovascular macular telangiectasia; **AND**
- Member does not have evidence of advanced disease that would preclude treatment of MacTel (e.g., significant retinal scarring and atrophy with retinal tissue that cannot be preserved); **AND**
- Member has an inner segment–outer segment junction line (IS/OS) photoreceptor break and area of ellipsoid zone (EZ) loss, as measured by spectral domain optical coherence tomography (SD-OCT), at between 0.16 mm^2 and 2.00 mm^2.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 IMPLANT)

2 billable units* (one single-dose implant containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF, per eye [*max units are based on administration to both eyes])

LENGTH OF AUTHORIZATION

One dose per eye, not eligible for renewal

ENHERTU® (FAM-TRASTUZUMAB DERUXTECAN-NXKI)

HCPCS: J9358

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as a single agent, unless otherwise specified; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation; **AND**
- Member meets indication specific criteria below:

Breast Cancer

- Member has high-risk, early-stage invasive or inflammatory breast cancer; **AND**
  - Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Used as neoadjuvant therapy for Stage II or III disease, followed by a taxane, trastuzumab, and pertuzumab (THP); **OR**
    - Used as adjuvant therapy for residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment; **OR**
- Member has unresectable or metastatic disease; **AND**
  - Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
  - Used as first-line therapy in combination with pertuzumab; **OR**
- Member has recurrent unresectable (local or regional) or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Used as subsequent therapy; **OR**
    - Used as first-line therapy in members who have experienced disease progression within 6 months of neoadjuvant or adjuvant therapy (12 months for pertuzumab-containing regimens); **OR**
  - Member has HER2-low or ultralow disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Member has hormone receptor-negative disease; **AND**
      - Used as subsequent therapy; **OR**
      - Member developed disease progression/recurrence during or within 6 months after completing adjuvant chemotherapy; **OR**
    - Member has hormone receptor-positive disease; **AND**
      - Used for previously treated disease with at least one line of endocrine-based therapy in the metastatic setting.

Gastric, Esophageal, and Esophagogastric Junction Cancers

- Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Member has adenocarcinoma histology; **AND**
- Member is not a surgical candidate OR has locally advanced, recurrent, or metastatic disease; **AND**
- Used as subsequent therapy.

Non-Small Cell Lung Cancer (NSCLC)

- Used as subsequent therapy; **AND**
  - Member has ERBB2 (HER2) mutation positive disease as determined by an FDA-approved or CLIA-complaint test; **AND**
    - Member has recurrent, advanced, unresectable, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **OR**
  - Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Member has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy.

HER2-Positive Solid Tumors

- Member has human epidermal growth factor receptor 2 (HER2)-positive solid tumors as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as monotherapy for unresectable or metastatic disease; **AND**
- Member has received prior systemic treatment and has no satisfactory alternative treatment options.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Left ventricular ejection fraction (LVEF) within the previous 3 months as follows:
  - LVEF is > 45% and absolute decrease is ≤ 20% from baseline; **OR**
  - LVEF is 40% to 45% and absolute decrease is < 10% from baseline.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

700 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ENJAYMO® (SUTIMLIMAB-JOME)

HCPCS: J1302

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member must be vaccinated against encapsulated bacteria [e.g., Streptococcus pneumoniae, Haemophilus influenzae (type B), Neisseria meningitidis (serogroups A, C, W, Y and B), etc.] at least two weeks prior to initiation of therapy in accordance with the most current Advisory Committee on Immunization Practices (ACIP) recommendations and will continue to be revaccinated in accordance with ACIP recommendations (Note: If urgent therapy is indicated in a member who is not up to date on their vaccines, administer vaccine(s) as soon as possible); **AND**
- Member does not have an active chronic systemic infection (e.g., hepatitis B, hepatitis C, or HIV, etc.); **AND**
- Will not be used in combination with another complement-inhibitor therapy or B-cell directed therapy (Note: Not applicable when sutimlimab is used as bridge therapy to B-cell directed treatment); **AND**
- Member does not have systemic lupus erythematosus (SLE) or other autoimmune disease with positive anti-nuclear antibody; **AND**
- Member will avoid cold exposure where possible; **AND**
- Member has a confirmed diagnosis of Cold-Agglutinin Disease (CAD) based on ALL of the following:
  - Chronic hemolysis
  - Positive polyspecific direct antiglobulin test (DAT)
  - Monospecific DAT strongly positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C
  - Immunoglobulin G (IgG) DAT ≤1+; **AND**
- Member has one of the following:
  - Recent blood transfusion within the previous 6 months (i.e., transfusion dependent); **OR**
  - No recent blood transfusion (i.e., within the previous 6 months or a history of >1 blood transfusion within the previous 12 months); **AND**
    - Member had an inadequate response, or has a contraindication or intolerance, to rituximab with/without bendamustine (Note: Excludes members who require urgent use of sutimlimab due to acute hemolysis where transfusion is likely); **AND**
- Other causes of secondary CAD have been ruled out such as coexisting diseases or conditions (i.e., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy, etc.) [NOTE: patients with a history of or concomitant low-grade lymphoproliferative disease are not subject to exclusion]; **AND**
- Documented baseline values for ALL of the following (necessary for renewal):
  - Hemoglobin (Hb) level ≤ 10 g/dL
  - Packed RBC transfusion requirement (NOTE: Only applies to patients that are transfusion dependent)

- Markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, lactate dehydrogenase [LDH], haptoglobin, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

770 billable units weekly for two doses, then 770 billable units every 2 weeks thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ENSPRYNG® (SATRALIZUMAB-MWGE)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS

120 mg on days 1, 15, 29, and then 120 mg every 4 weeks thereafter

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ENTYVIO® (VEDOLIZUMAB)

HCPCS: J3380

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units at weeks 0, 2, and 6, then 300 billable units every 8 weeks

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

EPKINLY® (EPCORITAMAB-BYSP)

HCPCS: J9321

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Prophylaxis for infection will be followed according to local guidelines (e.g., Pneumocystis jirovecii pneumonia (PJP), Herpes virus, etc.); **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member does not have primary central nervous system (CNS) lymphoma or CNS involvement of disease; **AND**
- Used in combination with lenalidomide and rituximab as subsequent therapy; **AND**
  - Member has relapsed or refractory follicular lymphoma; **OR**
- Used as a single agent and after at least two prior lines of systemic therapy; **AND**
  - Member has diffuse large B-cell Lymphoma (DLBCL) (including DLBCL, not otherwise specified), high-grade B-cell lymphoma, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
    - Used for partial response, progressive, relapsed, or refractory disease; **OR**
  - Member has follicular lymphoma OR histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**
    - Used for partial response, no response, progressive, relapsed, or refractory disease; **OR**
- Used in combination with GemOx (gemcitabine and oxaliplatin) as subsequent therapy; **AND**
  - Member has diffuse large B-cell Lymphoma (DLBCL), high-grade B-cell lymphomas, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified), HIV-related plasmablastic lymphoma), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
    - Used for primary refractory disease or relapsed disease <12 months after completion of first-line therapy AND member is a non-candidate for CAR T-cell therapy; **OR**
    - Used for relapsed disease >12 months after completion of first-line therapy AND no intention to proceed to transplant; **OR**
    - Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.16 MG)

1200 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

EPOPROSTENOL

HCPCS: J1325

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have congestive heart failure due to severe left ventricular systolic dysfunction; **AND**
- Member does not have pulmonary edema; **AND**
- Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND ALL of the following:
  - Member's diagnosis was confirmed by right heart catheterization; **AND**
  - Member has a mean pulmonary arterial pressure greater than 20 mmHg; **AND**
  - Member has a pulmonary capillary wedge pressure less than or equal to 15 mmHg; **AND**
  - Member has a pulmonary vascular resistance greater than or equal to 3 Wood units; **AND**
  - Member's World Health Organization (WHO) functional Class is II or greater; **AND**
  - ONE of the following:
    - The requested agent will be utilized as monotherapy; **OR**
    - The requested agent will be utilized for add-on therapy to existing monotherapy AND BOTH of the following:
      - Member has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
      - All agents in the regimen are from a different therapeutic class (e.g., PDE-5 inhibitors, endothelin receptor antagonist, soluble guanylate cyclase stimulator); **OR**
    - The requested agent will be utilized for add-on therapy to existing dual therapy AND ALL of the following:
      - Member is WHO functional class III or IV; **AND**
      - Member has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
      - All agents in the regimen are from a different therapeutic class (e.g., PDE-5 inhibitors, endothelin receptor antagonist, soluble guanylate cyclase stimulator); **OR**
    - The requested agent will be utilized as part of triple therapy in a treatment naive member AND both of the following:
      - Member is WHO functional class IV; **AND**
      - The 3 agents being utilized consist of: endothelin receptor antagonist (ERA) plus PDE5 inhibitor plus prostanoid; **AND**
- If the request is for a brand agent (Flolan®, Veletri®) member must have an intolerance, hypersensitivity, or contraindication to the generic equivalent that is not expected to occur with the brand agent; **OR**
  - There is support for the use of the requested brand agent over the generic equivalent; **AND**

- Prescribed by, or in consultation with, a specialist (e.g., cardiologist, pulmonologist); **AND**
- Member will NOT be using the requested agent in combination with another prostanoid agent for the requested indication.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

6 billable units every day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ERBITUX® (CETUXIMAB)

HCPCS: J9055

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets indication specific criteria below:

Colorectal Cancer

- Will not be used as part of an adjuvant treatment regimen; **AND**
- Member has not been previously treated with cetuximab or panitumumab; **AND**
  - Member has both KRAS and NRAS negative (wild-type) and BRAF V600E mutation negative (wild-type) disease as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **AND**
    - Used as primary treatment for metastatic or unresectable (or medically inoperable) disease; **AND**
      - Used in combination with FOLFIRI; **OR**
    - Used as subsequent therapy for advanced or metastatic disease; **AND**
      - Used as a single agent; **AND**
        - Member has oxaliplatin- and irinotecan-refractory disease; **OR**
        - Member has irinotecan-intolerant disease; **OR**
      - Used in combination with irinotecan; **AND**
        - Member has irinotecan-refractory disease; **OR**
  - Member has BRAF V600E mutation positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Used in combination with encorafenib.

Head and Neck Cancer

- Member has squamous cell carcinoma; **AND**
  - Used in combination with radiation therapy as a single agent; **OR**
  - Used as first-line therapy; **AND**
    - Used in combination with platinum-based therapy with fluorouracil for unresectable, recurrent/persistent, or metastatic disease; **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent for unresectable, recurrent/persistent, or metastatic disease after platinum-based therapy.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

100 billable units for 1 dose then 130 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

EVENITY® (ROMOSOZUMAB-AQQG)

HCPCS: J3111

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Member must not have hypocalcemia; **AND**
- Member has not had a myocardial infarction or stroke within the preceding year; **AND**
- Will not be used in combination with bisphosphonates, denosumab, or parathyroid hormone analogs/related peptides; **AND**
- Member is a postmenopausal female; **AND**
- Member must be at a high risk for fracture; **AND**
- Member has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - T-score by DXA of ≤-2.5 in the lumbar spine, femoral neck, total hip or forearm at the 33% (one-third) radius site; **OR**
  - History of fragility fracture to the hip or spine, regardless of T-score; **OR**
  - T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **AND**
    - History of fracture of proximal humerus, pelvis, or distal forearm; **OR**
    - FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Member has one of the following:
  - Documented treatment failure or ineffective response to a minimum twelve month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
  - Member has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; **AND**
- Member has one of the following:
  - Documented treatment failure or ineffective response to a minimum (12) month trial on previous therapy with RANKL-blocking agents such as denosumab, etc.; **OR**
  - Member has a documented contraindication or intolerance to RANKL-blocking agents such as denosumab, etc.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

210 billable units every month for 12 doses

LENGTH OF AUTHORIZATION

12 months for initial approval, not eligible for renewal

EVKEEZA® (EVINACUMAB-DGNB)

HCPCS: J1305

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Baseline low-density lipoprotein cholesterol (LDL-C) labs have been obtained prior to initiating treatment (required for renewal); **AND**
- Member does not have a diagnosis of heterozygous familial hypercholesterolemia (HeFH); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Member has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Confirmed DNA test for functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality (i.e., LDLR, PCSK9, or apoB gene(s)); **OR**
  - Untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels in both parents consistent with HeFH; **AND**
- Must be used as an adjunct to a low-fat or heart-healthy diet; **AND**
- Member has been receiving stable background lipid lowering therapy for at least 4 weeks; **AND**
- Therapy will be used in conjunction with other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, lomitapide, LDL apheresis, etc.); **AND**
  - Member has tried and failed at least a 6-month trial of adherent therapy with maximally tolerated doses of lomitapide; **OR**
  - Member meets both of the following:
    - Member has tried and failed at least a 3-month trial of adherent therapy with: ezetimibe used in combination with the highest available (or maximally tolerated) dose of atorvastatin OR rosuvastatin, unless contraindicated; **AND**
    - Member has tried and failed at least a 3-month trial of adherent therapy with: combination therapy consisting of the highest available (or maximally tolerated) dose of atorvastatin OR rosuvastatin, ezetimibe, AND a PCSK9 inhibitor indicated for HoFH (e.g., evolocumab, alirocumab , unless contraindicated; **AND**
- Despite receiving LDL-lowering therapy, unless contraindicated, the member's LDL cholesterol ≥ 100 mg/dL (or ≥ 70 mg/dL for members with clinical atherosclerotic cardiovascular disease [ASCVD]).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

345 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

EXDENSUR® (DEPEMOKIMAB-ULAA)

HCPCS: J2361

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 12 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Member has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 150 cells/µL; **AND**
- Exdensur will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, mepolizumab, benralizumab, dupilumab, tezepelumab-ekko); **AND**
- Exdensur will be used as add-on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1); **AND**
- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- 100 billable units every 6 months

Definitions

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

EXONDYS 51® (ETEPLIRSEN)

HCPCS: J1428

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a confirmed diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping; **AND**
- Member has been on a stable dose of corticosteroids (unless contraindicated or intolerant); **AND**
- Member will not be using any other exon skipping agents for DMD.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

1400 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

FABRAZYME® (AGALSIDASE BETA)

HCPCS: J0180

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age; **AND**
- Must not be used in combination with migalastat or pegunigalsidase alfa-iwxj; **AND**
- Member has a documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Deficiency in α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells (males only); **OR**
  - Detection of pathogenic mutations in the GLA gene by molecular genetic testing; **AND**
- Member has a baseline of one or more of the following:
  - Tissue globotriaosylceramide (Gb3/GL-3) inclusions
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3)
  - Clinical signs and/or symptoms of disease (e.g., dermatologic, gastrointestinal, pulmonary, vascular, renal, cardiac, neurologic manifestations).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

115 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

FASENRA® (BENRALIZUMAB)

HCPCS: J0517

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

Severe Asthma

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Member has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 150 cells/µL; **AND**
- Fasenra will not be co-administered with another monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Fasenra will be used as add-on maintenance treatment in members regularly receiving both of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1).

Eosinophilic granulomatosis with polyangiitis (EGPA)

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of EGPA§; **AND**
- Member has blood eosinophils greater than or equal to 1000 cells/µL or greater than 10% of leukocytes; **AND**
- Member is currently on maximally tolerated oral corticosteroid therapy or has an intolerance, hypersensitivity or contraindication to oral corticosteroid therapy; **AND**
- Member's physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses).

Hypereosinophilic Syndrome (HES)

- Member is at least 12 years of age; **AND**

- Member has been diagnosed with HES (without an identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1- PDGFRα kinase-positive HES) for at least 6 months prior to starting treatment; **AND**
- Fasenra will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, mepolizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member has a history of two or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
- Fasenra will be used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy.

RENEWAL CRITERIA

Severe Asthma

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

Eosinophilic granulomatosis with polyangiitis (EPGA)

- Member has disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
  - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of $\leq$ 4 mg]
  - Decrease in maintenance dose of systemic corticosteroids
  - Improvement in BVAS score compared to baseline
  - Improvement in asthma symptoms or asthma exacerbations
  - Improvement in duration of remission or decrease in the rate of relapses

Hypereosinophilic syndrome (HES)

- Member has had a disease response as indicated by a decrease in HES flares from baseline. Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least two occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Severe Asthma

- 30 billable units every 28 days for the first 3 doses, then 30 billable units every 56 days

Eosinophilic Granulomatosis with polyangiitis (EPGA), Hypereosinophilic Syndrome (HES)

- 30 billable units every 28 days

Definitions

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive)**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

§ Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all of the following:

- History or presence of asthma
- Blood eosinophil level greater than 10% or an absolute count greater than 1000 cells/mm3
- Two or more of the following criteria:
  - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates
  - Sinonasal abnormalities
  - Cardiomyopathy
  - Glomerulonephritis
  - Alveolar hemorrhage
  - Palpable purpura
  - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

FASLODEX® (FULVESTRANT)

HCPCS: J9393, J9394, J9395

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; **AND**
  - Member has advanced disease and has not previously been treated with endocrine therapy; **AND**
    - Member is postmenopausal female (sex assigned at birth); **OR**
  - Member has advanced or metastatic disease; **AND**
    - Will be used in combination with ribociclib as initial endocrine based therapy or following disease progression on endocrine therapy; **AND**
      - Member is postmenopausal female (sex assigned at birth); **OR**
    - Will be used in combination with palbociclib or abemaciclib following disease progression after endocrine therapy; **OR**
- Member has HR-positive advanced breast cancer with disease progression following endocrine therapy; **AND**
  - Member is postmenopausal female (sex assigned at birth).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 25 MG)

20 billable units every 14 days for 3 doses then 20 billable units every 28 days thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

FIRMAGON® (DEGARELIX)

HCPCS: J9155

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of advanced prostate cancer.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

240 billable units for one dose then 80 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

FOLOTYN® (PRALATREXATE)

HCPCS: J9307

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of Peripheral T-Cell Lymphoma (PTCL); **AND**
- Used as a single agent; **AND**
  - Used as initial palliative intent therapy; **OR**
  - Used as subsequent treatment for relapsed or refractory disease; **AND**
- Member has one of the following PTCL sub-types:
  - Anaplastic large cell lymphoma (ALCL)
  - Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
  - Angioimmunoblastic T-cell lymphoma (AITL)
  - Enteropathy-associated T-cell lymphoma (EATL)
  - Monomorphic epitheliotropic intestinal T-Cell lymphoma (MEITL)
  - Nodal peripheral T-Cell lymphoma with TFH phenotype (PTCL, TFH)
  - Follicular T-Cell lymphoma (FTCL).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

80 billable units weekly for 6 doses in a 7-week cycle

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

FORTEO (TERIPARATIDE)

HCPCS: J3110

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is 18 years of age or older; **AND**
- Member has a confirmed diagnosis of osteoporosis; **AND**
- Member has experienced a therapeutic failure or inadequate response to at least two bisphosphonates (unless unable to receive or contraindicated); **AND**
- Member has a history of osteoporotic fracture; **OR**
  - Member is at high risk for fractures; **AND**
- Member has a bone mineral density of -3 or worse; **OR**
  - Documented Hip DXA (femoral neck or total hip) or lumbar spine T-score -2.5 (standard deviations) or below; **AND**
- Member will be taking calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Member has one of the following:
  - Member is a postmenopausal female; **OR**
  - Member is a male with primary or hypogonadal osteoporosis; **OR**
  - Osteoporosis associated with sustained systemic glucocorticoid therapy (for example, more than 6 months use of greater than 7.5 mg per day of prednisone or an equivalent); **AND**
- Member is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, bone metastases or skeletal malignancies, etc.); **AND**
- Member has not received therapy with parathyroid hormone analogs (e.g., Forteo) in excess of 24 months in total.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MCG)

2 billable units per day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal; maximum of 24 months of treatment per lifetime

FOSAPREPITANT

HCPCS: J1434, J1453, J1456

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1800 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

FRAGMIN® (DALTEPARIN)

HCPCS: J1645

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and meets age requirements; **AND**
- Member must have tried and failed the preferred product on the PDL, enoxaparin.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2500 IU)

8 billable units per day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

FUROSCIX® (FUROSEMIDE)

HCPCS: J1941

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is 6 years of age or older and weighs ≥ 43 kg; **AND**
- Medication is prescribed by or in consultation with a cardiologist or nephrologist; **AND**
- Member does not have any of the following:
  - Anuria
  - Hepatic cirrhosis or ascites
  - Acute pulmonary edema; **AND**
- Member has a diagnosis of chronic heart failure or chronic kidney disease (including nephrotic syndrome); **AND**
- Member is experiencing edema and prescriber attests that Furoscix is not being used for an emergency; **AND**
- Prescriber attests that the member requires non-oral route of administration of a loop diuretic for edema in chronic heart failure or chronic kidney disease, including nephrotic syndrome; **AND**
- Prescriber attests that the member will be monitored outpatient for fluid, electrolyte, and metabolic abnormalities.

QUANTITY LIMITS (1 BILLABLE UNIT = 20 MG)

12 billable units every 90 days

LENGTH OF AUTHORIZATION

90 days

FYARRO® (SIROLIMUS ALBUMIN-BOUND)

HCPCS: J9331

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin; **AND**
- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Member does not have uncontrolled or symptomatic CNS metastases (controlled and asymptomatic CNS metastases are allowed); **AND**
- Member has not had prior treatment with and will not be used in combination with other mTOR inhibitors; **AND**
- Member does not have lymphangioleiomyomatosis (LAM); **AND**
- Used as single agent therapy; **AND**
- Member has a diagnosis of Perivascular Epithelioid Cell Tumor (PEComa); **AND**
- Member has locally advanced unresectable or metastatic malignant disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

600 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

FYLNETRA® (PEGFILGRASTIM-PBBK)

HCPCS: Q5130

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

GAMIFANT® (EMAPALUMAB-LZSG)

HCPCS: J9210

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Providers will monitor and consider prophylaxis in members for Herpes Zoster, Pneumocystis Jirovecii, and fungal infections; **AND**
- Member does not have an active infection, including clinically important localized infections that are favored by interferon-gamma neutralization (e.g., infections caused by mycobacteria, Histoplasma Capsulatum, etc.); **AND**
- Must not be administered concurrently with live or live attenuated vaccines; **AND**
- Member meets indication specific criteria below:

Primary Hemophagocytic Lymphohistiocytosis (HLH)

- Member has a definitive diagnosis of HLH as indicated by the following:
  - Member diagnosis of primary HLH based on identification of biallelic pathogenic gene variants from molecular genetic testing (e.g., PRF1, UNC13D, STX11, or STXBP2) or a family history consistent with primary HLH; **OR**
  - Member has at least FIVE of the following eight documented criteria:
    - Prolonged fever (> 7 days)
    - Splenomegaly
    - Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
    - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L)
    - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    - Low or absent NK-cell activity
    - Ferritin ≥ 500 mcg/L
    - Soluble CD25 (aka soluble IL-2Rα receptor) ≥ 2400 U/mL; **AND**
- Member has active, primary disease that is refractory, recurrent, or progressive during treatment with conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporine A, anti-thymocyte globulin, etc.) unless member is intolerant to conventional HLH therapy; **AND**
- Member has NOT received hematopoietic stem cell transplant (HSCT); **AND**
- Used in combination with dexamethasone (Note: Patients currently on oral cyclosporine A, or intrathecal methotrexate and/or glucocorticoids may continue on therapy while treated with emapalumab).

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS)

- Member has a definitive diagnosis of HLH/MAS as indicated by BOTH of the following:
  - Ferritin >684 ng/mL; **AND**
  - At least two of the following:
    - Platelet count ≤181×10^9/L
    - AST >48 U/L
    - Triglycerides >156 mg/dL
    - Fibrinogen levels ≤360 mg/dL; **AND**
- Member has known or suspected diagnosis of Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) or Adult Onset Still's Disease (AOSD); **AND**
- Member has had an inadequate response or intolerance to high-dose intravenous (IV) glucocorticoids OR has experienced recurrent MAS.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

9250 billable units per 30 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

GAZYVA® (OBINUTUZUMAB)

HCPCS: J9301

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Member has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and members with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Member meets indication specific criteria below:

Chronic Lymphocytic Leukemia (CLL)

- Used as first-line therapy; **AND**
  - Used in combination with chlorambucil.

Follicular Lymphoma

- Used as first-line therapy; **AND**
  - Used in combination with chemotherapy [e.g., bendamustine or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or CVP (cyclophosphamide, vincristine, prednisone)]; **OR**
- Used as subsequent therapy for no response, relapsed, refractory, or progressive disease (if not previously given); **AND**
  - Used in combination with chemotherapy [e.g., bendamustine, CHOP, or CVP]; **OR**
  - Used in combination with lenalidomide; **OR**
  - Used as a single agent; **OR**
- Used as third-line and subsequent therapy for no response, relapsed, or progressive disease; **AND**
  - Used in combination with zanubrutinib; **OR**
- Used as a single agent for maintenance therapy; **AND**
  - Used as first-line extended therapy following chemoimmunotherapy; **OR**
  - Used as second-line extended therapy for rituximab-refractory disease; **OR**
- Used as a substitute for rituximab in members with intolerance to rituximab (including those experiencing severe hypersensitivity reactions requiring discontinuation of rituximab) or experiencing rare complications such as mucocutaneous reactions.

Lupus Nephritis (LN)

- Member has a diagnosis of active class III, IV, or V lupus nephritis as confirmed via kidney biopsy; **AND**
- Member will be using background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide) in combination; **AND**

- Member does not have severe active central nervous system (CNS) lupus.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member has been evaluated for the presence of progressive multifocal leukoencephalopathy (PML) and has been found to be negative.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Chronic Lymphocytic Leukemia

- Initial Cycle:10 billable units on day 1, 90 billable units on day 2, 100 billable units on day 3, 200 billable units on days 8 and 15 (21 day cycle)
- Subsequent cycles: 200 billable units every 21 days

Follicular Lymphoma

- Initial cycle: 100 billable units every 7 days x 4 doses
- Subsequent cycles: 100 billable units every 21 days

Lupus Nephritis

- Initial: 100 billable units weeks 0, 2, 24, and 26
- Maintenance: 100 billable units every 6 months

LENGTH OF AUTHORIZATION

Lupus Nephritis

- 12 months for initial approval, 12 months for renewal

All other indications

- 6 months for initial approval, 6 months for renewal

GIVLAARI® (GIVOSIRAN)

HCPCS: J0223

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member will avoid known triggers of porphyria attacks (i.e., alcohol, smoking, exogenous hormones, hypocaloric diet/fasting, certain medications such as barbiturates, hydantoins, sulfa-antibiotics, anti-epileptics, etc.); **AND**
- Member has not had or is not anticipating a liver transplant; **AND**
- Member has a definitive diagnosis of acute hepatic porphyria (including acute intermittent porphyria, variegate porphyria, hereditary coproporphyria, or ALA dehydratase deficient porphyria) as evidenced by one of the following:
  - Member has had elevated urinary or plasma PBG (porphobilinogen) and ALA (delta-aminolevulinic acid) levels within the previous year; **OR**
  - Member has a mutation in an affected gene as identified on molecular genetic testing; **AND**
- Member has a history of at least two documented porphyria attacks (i.e., requirement of hospitalization, urgent healthcare visit or intravenous administration of hemin) OR one severe attack with CNS involvement (e.g., hallucinations, seizures, etc.) during the previous six months; **AND**
- Members currently receiving prophylactic intravenous hemin therapy will discontinue hemin within 3 to 6 months following initiation of givosiran.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

756 billable units every month

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

GRAFAPEX™ (TREOSULFAN)

HCPCS: J0614

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Member has Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS); **AND**
- Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has not received a prior allo-HSCT; **AND**
- Used in combination with fludarabine as a preparative regimen prior to allo-HSCT; **AND**
- Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GVHD, infections, etc.) according to institutional guidelines.

QUANTITY LIMITS (1 BILLABLE UNIT = 50 MG)

1500 billable units (500 billable units on day -4, day -3 and day -2 before stem cell transplant)

LENGTH OF AUTHORIZATION

6 months for initial approval, not eligible for renewal

GRANISETRON

HCPCS: J1626

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered prior to surgery or alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 100 MCG)

10 billable units every day

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

GRANIX® (TBO-FILGRASTIM)

HCPCS: J1447

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

1560 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

HAEGARDA® (C1 ESTERASE INHIBITOR, HUMAN)

HCPCS: J0599

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used for prophylaxis of hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Member has tried and failed two preferred agents listed in the Hereditary Angioedema (HAE) Agents Class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 IU)

5600 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

HALAVEN® (ERIBULIN)

HCPCS: J9179

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets indication specific criteria below:

Breast Cancer

- Member has metastatic disease; **AND**
  - Used as a single agent for members who have previously received at least two chemotherapy regimens for the treatment of metastatic disease; **AND**
  - Prior therapy includes treatment with an anthracycline and a taxane in either the adjuvant or metastatic setting.

Liposarcoma

- Used as a single agent; **AND**
- Member has unresectable or metastatic or recurrent disease; **AND**
- Member has received a prior anthracycline-containing regimen (e.g., doxorubicin, liposomal doxorubicin, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

80 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

HEMGENIX® (ETRANACOGENE DEZAPARVOVEC-DRLB)

HCPCS: J1411

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of moderately severe or severe congenital factor IX deficiency (i.e., ≤ 2% of normal circulating factor IX), as confirmed by blood coagulation testing, for which the subject is on continuous routine factor IX prophylaxis, unless there is a contraindication or intolerance (**Note**: continuous routine prophylaxis is defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks, etc.) as documented in the medical records); **AND**
- Member has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Member has one or more of the following:
  - Currently use Factor IX prophylaxis therapy; **OR**
  - Have current or historical life-threatening hemorrhage; **OR**
  - Have repeated, serious spontaneous bleeding episodes, (e.g., intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life - threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding); **AND**
- Member has been tested and found negative for Factor IX inhibitor titers (if test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Hemgenix should not be given); **AND**
- Member Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled (note: members will continue to require exogenous Factor IX until response to Hemgenix occurs); **AND**
- Member will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from etranacogene dezaparvovec treatment; **AND**
- Member must have a baseline anti-AAV5 antibody titer of ≤ 1:678 measured by ELISA (Note: this assay was used in the HOPE-B clinical trial and is assessable via CSL Behring); **AND**
- Member will have baseline liver function assessed prior to and after therapy, weekly, for at least 3 months; **AND**
- Members with preexisting risk factors for hepatocellular carcinoma (e.g., members with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit for one dose

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

HEPZATO™ (MELPHALAN HYDROCHLORIDE)

HCPCS: J9248

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age and weighs ≥ 35 kg ; **AND**
- Used as a single agent; **AND**
- Member does not have any of the following contraindications to treatment:
  - Active intracranial metastases or brain lesions with a propensity to bleed
  - Liver failure (i.e., Child-Pugh Class B or C cirrhosis), portal hypertension, or known varices at risk for bleeding
  - Surgery or medical treatment of the liver in the previous 4 weeks
  - Uncorrectable coagulopathy
  - Inability to safely undergo general anesthesia, including active cardiac conditions including, but not limited to, unstable coronary syndromes (unstable or severe angina or myocardial infarction), worsening or new-onset congestive heart failure, significant arrhythmias, or severe valvular disease
  - History of allergies or known hypersensitivity to a component or material utilized within the Hepzato Kit including: history of allergy to natural rubber latex, history of allergy or hypersensitivity to heparin or presence of heparin-induced thrombocytopenia (HIT), or history of severe allergic reaction to iodinated contrast not controlled by premedication with antihistamines and steroids; **AND**
- Member does not have active hepatitis B or C infection; **AND**
- Member has the following hematological indices at baseline and subsequently, prior to each infusion:
  - Hemoglobin ≥ 10 g/dL; **AND**
  - Platelets ≥ 100,000/microliter; **AND**
  - Neutrophils > 2000/microliter; **AND**
- Member will discontinue oral anticoagulation and drugs affecting platelet function, and ACE-inhibitors, calcium channel blockers, or alpha-1-adrenergic blockers prior to the procedure; **AND**
- Member has a diagnosis of Uveal Melanoma; **AND**
  - Member has unresectable hepatic metastases; **AND**
    - Member has ≤ 50% histologically or cytologically-proven ocular melanoma metastases in the parenchyma of the liver AND no extrahepatic disease; **OR**
  - Member has limited extrahepatic disease (disease limited to the bone, lymph nodes, subcutaneous tissues, or lung) that is amenable to resection or radiation; **OR**
  - Used as regional percutaneous hepatic perfusion for hepatic dominant disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**

- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

250 billable units every 6 weeks for a total of 6 treatments

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal for up to a maximum of 6 total treatments

HERCEPTIN HYLECTA® (TRASTUZUMAB AND HYALURONIDASE-OYSK)

HCPCS: J9356

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for 7 months after the last dose; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab (or any of its biosimilar products) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Member has a diagnosis of HER2 overexpressing Breast Cancer; **AND**
- Used as adjuvant therapy; **AND**
  - Used as a single agent following multi-modality anthracycline-based therapy; **OR**
  - Used as part of a treatment regimen with docetaxel and carboplatin; **OR**
  - Used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; **OR**
- Used for metastatic disease; **AND**
  - Used as a single agent in members who have received one or more prior chemotherapy regimens for metastatic disease; **OR**
  - Used in combination with paclitaxel for first-line treatment.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Left ventricular ejection fraction (LVEF) within the previous 3 months as follows:
  - LVEF is within the institutional normal limits, and has not had an absolute decrease of ≥ 16% from pre-treatment baseline; **OR**
  - LVEF is below the institutional lower limits of normal and has not had an absolute decrease of ≥ 10% from pre-treatment baseline.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

60 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ICATIBANT (GENERIC FIRAZYR®)

HCPCS: J1744

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used as monotherapy for treatment of acute hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

360 billable units per 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ILARIS® (CANAKINUMAB)

HCPCS: J0638

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Cryopyrin-Associated Periodic Syndromes

- 150 billable units every 56 days

Gout Flare

- 150 billable units every 84 days

All other indications

- 300 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ILUMYA® (TILDRAKIZUMAB-ASMN)

HCPCS: J3245

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

100 billable units at weeks 0 and 4, then 100 billable units every 12 weeks

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ILUVIEN® (FLUOCINONIDE ACETONIDE IMPLANT)

HCPCS: J7313

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections (including active epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella, mycobacterial infections and fungal diseases, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member does not have glaucoma with a cup to disk ratio greater than 0.8; **AND**
- Member does not have a torn or ruptured posterior lens capsule; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Member meets indication specific criteria below:

Diabetic Macular Edema (DME)

- Member has been previously treated with a course of corticosteroids; **AND**
- Member did not have a clinically significant rise in intraocular pressure from prior corticosteroid treatment.

Chronic non-infectious uveitis affecting the posterior segment of the eye

- Member has had chronic disease for at least one year; **AND**
- Other causes of uveitis have been ruled out (e.g., infection, malignancy, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.01 MG)

38 billable units every 36 months

LENGTH OF AUTHORIZATION

36 months for initial approval, 36 months for renewal

IMAAVY™ (NIPOCALIMAB-AAHU)

HCPCS: J9256

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 12 years of age; **AND**
- Member has a diagnosis of generalized Myasthenia Gravis (gMG) **and all** of the following:
  - **One** of the following:
    - Member has a positive serological test for anti-AChR antibodies; **OR**
    - Member has a positive serological test for anti-MuSK antibodies; **AND**
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - Member has a MG-Activities of Daily Living total score of greater than or equal to 6; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
- Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis; **AND**
- Member will **not** be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Rystiggo (rozanolixizumab-noli).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 3 MG)

Initial treatment

- 1200 billable units

All subsequent treatments

- 600 billable units occurring 2 weeks after previous treatment

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

IMDELLTRA® (TARLATAMAB-DLLE)

HCPCS: J9026

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member will be closely monitored for signs and symptoms of Cytokine release syndrome (CRS), neurologic toxicity and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) during treatment; **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Used as a single agent; **AND**
- Member has extensive stage Small Cell Lung Cancer (ES-SCLC); **AND**
- Used as subsequent therapy following disease progression on or after platinum-based chemotherapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- Cycle 1: 1 billable unit on day 1, followed by 10 billable units on days 8 and 15 of a 28 day cycle
- Cycle 2 and subsequent: 20 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

IMFINZI® (DURVALUMAB)

HCPCS: J9173

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified; **AND**
- Member meets indication specific criteria below:

Non-Small Cell Lung Cancer (NSCLC)

- Used as a single agent for consolidation therapy; **AND**
  - Member has unresectable stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy; **OR**
- Used as neoadjuvant therapy; **AND**
  - Member has resectable disease (tumors ≥4 cm or node positive); **AND**
  - Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; **AND**
  - Member has no known EGFR mutations or ALK rearrangements; **OR**
- Used adjuvant therapy; **AND**
  - Used as a single agent following previous neoadjuvant durvalumab plus chemotherapy and surgery; **AND**
  - Member has no known EGFR mutations or ALK rearrangements; **OR**
- Member has recurrent, advanced, or metastatic disease; **AND**
  - Used in combination with tremelimumab-actl and platinum-based chemotherapy; **AND**
  - Member does not have sensitizing EGFR mutations or ALK genomic tumor aberrations.

Small Cell Lung Cancer (SCLC)

- Member has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin; **OR**
- Member has limited stage disease (LS-SCLC); **AND**
  - Used as single agent therapy; **AND**
  - Used if disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; **OR**
- Used as subsequent treatment if there is a prolonged disease free interval; **AND**
  - Member has progressive or relapsed disease; **AND**
  - Used in combination with etoposide and either carboplatin or cisplatin, followed by single agent maintenance.

Biliary Tract Cancers

- Used in combination with cisplatin (or carboplatin if ineligible for cisplatin) and gemcitabine; **AND**
  - Used as primary treatment for unresectable, gross residual (R2), locally advanced, or metastatic disease; **OR**
  - Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant therapy; **OR**
  - Used as subsequent treatment for progression on or after systemic treatment for unresectable, gross residual (R2), or metastatic disease.

Hepatocellular Carcinoma (HCC)

- Used in combination with tremelimumab-actl; **AND**
  - Used as first-line therapy; **AND**
    - Member has unresectable disease.

Gastric or Gastroesophageal Junction Adenocarcinoma

- Member has adenocarcinoma; **AND**
  - Used in combination with FLOT (Fluorouracil, leucovorin, oxaliplatin, and docetaxel); **AND**
    - Used as neoadjuvant and adjuvant therapy; **OR**
  - Used as a single-agent; **AND**
    - Used as adjuvant therapy following resection and previous adjuvant use in combination with FLOT.

Endometrial Cancer

- Member has mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used in combination with carboplatin and paclitaxel, and continued as single agent maintenance therapy; **AND**
  - Used for primary advanced or recurrent disease.

Bladder Cancer

- Member has muscle invasive bladder cancer (MIBC); **AND**
  - Member has stage II (cT2, N0) or IIIA (cT3, N0; cT4a, N0; cT1-4a, N1) disease; **AND**
    - Used in combination with cisplatin and gemcitabine as neoadjuvant therapy prior to cystectomy; **OR**
    - Used as a single-agent as adjuvant therapy following cystectomy; **AND**
      - Member received initial therapy with durvalumab, cisplatin, and gemcitabine; **OR**
- Member has BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC); **AND**
  - Used in combination with Bacillus Calmette-Guerin (BCG)

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Non-Small Cell Lung Cancer, Small Cell Lung Cancer

- 672 billable units every 84 days

Gastric or Gastroesophageal Junction Adenocarcinoma

- 150 billable units every 28 days for 14 doses

Biliary Tract Cancer

- 150 billable units every 21 days for 8 doses, then 150 billable units every 28 days

Hepatocellular Carcinoma

- 150 billable units every 28 days

Endometrial Cancer

- 112 billable units every 21 days for 6 doses, then 150 billable units every 28 days

Bladder Cancer

- MIBC: 150 billable units every 21 days for 4 doses, then 150 billable units every 28 days for 8 doses
- NMIBC: 150 billable units every 28 days for 13 doses

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

IMJUDO® (TREMELIMUMAB-ACTL)

HCPCS: J9347

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets indication specific criteria below:

Hepatocellular Carcinoma (HCC)

- Used in combination with durvalumab; **AND**
- Member has unresectable disease.

Non-Small Cell Lung Cancer (NSCLC)

- Member has recurrent, advanced, or metastatic disease; **AND**
- Used in combination with durvalumab and platinum-based chemotherapy; **AND**
- Member does not have sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Hepatocellular Carcinoma

- 300 billable units one time only

Non-Small Cell Lung Cancer

- 75 billable units every 21 days for 4 doses, followed by 75 billable units for one dose on day 112

LENGTH OF AUTHORIZATION

Hepatocellular Carcinoma

- One dose only, not eligible for renewal

Non-Small Cell Lung Cancer

- 4 months for initial approval, not eligible for renewal

IMLYGIC® (TALIMOGENE LAHERPAREPVEC)

HCPCS: J9325

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is not pregnant (**Note**: women of childbearing potential should be advised to use an effective method of contraception to prevent pregnancy during treatment); **AND**
- Member is not immunocompromised (i.e., members with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy); **AND**
- Treatment will be administered via intralesional injection; **AND**
- Used for unresectable cutaneous, subcutaneous, and nodal lesions in members with melanoma recurrent after initial surgery.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MILLION PFU)

Initial treatment

- 4 billable units

Second treatment

- 400 billable units occurring 3 weeks after initial treatment

All subsequent treatments

- 400 billable units occurring 2 weeks after previous treatment

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

INFLIXIMAB (AND BIOSIMILARS)

HCPCS: J1745, J1748, Q5102, Q5103, Q5104, Q5109, Q5121

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Rheumatoid Arthritis

- 40 billable units at weeks 0, 2, and 6, then every 56 days

Ankylosing Spondylitis

- 60 billable units at weeks 0, 2, and 6, then every 42 days

Crohn's Disease, Ulcerative Colitis, Psoriatic Arthritis, Plaque Psoriasis

- 60 billable units at weeks 0, 2, and 6, then every 42 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

INLEXZO™ (GEMCITABINE INTRAVESICAL)

HCPCS: J9183

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Will not be used concurrently with other gemcitabine formulations; **AND**
- Member does not have a hypersensitivity to any gemcitabine formulations; **AND**
- Member will be evaluated for perforation of the bladder and mucosal compromise and, if present, will not receive therapy until bladder integrity has been restored; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**
- Member is not a candidate for generically available gemcitabine instilled intravesically; **AND**
- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) (with or without papillary tumors); **AND**
- Member has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) (defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of completion of adequate BCG therapy); **AND**
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components) (Note: Members with residual CIS that is not amenable to complete resection is permitted); **AND**
- Member does NOT have muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e., urethra, ureter, or renal pelvis) urothelial carcinoma.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit every 3 weeks for 6 months (8 doses), followed by 1 billable unit every 12 weeks for 18 months (6 doses)

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ISTODAX® (ROMIDEPSIN)

HCPCS: J9318, J9319

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of Cutaneous T-Cell Lymphoma (CTCL); **AND**
- Member has failed prior systemic therapy.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

1200 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE)

HCPCS: J3405

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age or older; **AND**
- Member has not received prior treatment with spinal muscular atrophy (SMA) gene therapy (e.g., onasemnogene abeparvovec-xioi [Zolgensma], etc.); **AND**
- Member has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the survival motor neuron 1 (SMN1) gene; **AND**
- Member must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA; **AND**
- Baseline liver function will be assessed prior to initiating therapy and will continue to be monitored for at least 3 months after therapy; **AND**
- Used concomitantly with systemic corticosteroids; **AND**
- Member does not have advanced disease (complete limb paralysis, permanent ventilation support, etc.); **AND**
- Will not be used in combination with other SMN-targeting agents for SMA (e.g., nusinersen, risdiplam, onasemnogene abeparvovec-xioi, etc.).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 treatment of up to 1.2×10^{14} vector genomes)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

IVIG (IMMUNE GLOBULIN IV)*

HCPCS: J1459, J1552, J1553, J1554, J1556, J1557, J1561, J1566, J1568, J1569, J1572, J1576, J1577, J1599

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**

Primary Immunodeficiency

Such as: Wiskott-Aldrich syndrome, x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, antibody deficiency with near normal immunoglobulin levels, and combined deficiencies (severe combined immunodeficiencies, ataxiatelangiectasia, x-linked lymphoproliferative syndrome) *[list not all inclusive]*

- Member has an IgG level < 200 mg/dL; **OR**
- Member meets both of the following:
  - Member has a history of multiple hard to treat infections as indicated by at least one of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent, deep skin or organ abscesses
    - Persistent thrush in the mouth or fungal infections on the skin
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia
    - Family history of PID; **AND**
  - Member has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura

For acute ITP:

- Used to manage acute bleeding due to severe thrombocytopenia (platelet count < 30 X 10^9/L); **OR**
- Used to increase platelet counts prior to invasive surgical procedures such as splenectomy (platelet count < 100 X 10^9/L); **OR**
- Member has severe thrombocytopenia (platelet count < 20 X 10^9/L)

For chronic ITP:

- Member is at increased risk for bleeding as indicated by a platelet count < 30 X 10^9/L; **AND**
- Member has a history of failure, contraindication, or intolerance to corticosteroids; **AND**
- Duration of illness > 6 months.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Member's disease course is progressive or relapsing and remitting for >2 months; **AND**

- Member has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
  - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
  - Prolonged distal motor latency in at least 2 motor nerves; **OR**
  - Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Prolonged F wave latency in at least 2 motor nerves; **AND**
- Member is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

Multifocal Motor Neuropathy

- Member has progressive, focal, asymmetric limb weakness (without sensory symptoms) for >1 month; **AND**
- Member has complete or partial conduction block or abnormal temporal dispersion conduction in at least 2 motor nerves; **AND**
- Member has normal sensory nerve conduction on all nerves tested; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.).

Dermatomyositis

- Member has severe active disease; **AND**
  - Member has proximal weakness in all upper and/or lower limbs; **AND**
    - Member has one or more of the following:
      - Muscle biopsy proven dermatomyositis
      - Dermatomyositis with classic skin manifestations (i.e., heliotrope rash or Gottron’s papules); **OR**
  - Member has clinically amyopathic dermatomyositis (CADM; historically termed "dermatomyositis sine myositis"); **AND**
- Member has failed a trial of corticosteroids (i.e., prednisone); **AND**
- Member has failed a trial of an immunosuppressant (e.g., methotrexate, azathioprine, etc.); **AND**
- Member will be on combination therapy with corticosteroids or other immunosuppressants; **AND**
- Member has a documented baseline physical exam and muscular strength/function.

Kawasaki’s Disease

- Approvable with confirmation of diagnosis.

Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia

- Member has an IgG level < 200 mg/dL; **OR**
- Member has an IgG level < 500 mg/dL; **AND**
  - Member has recurrent sinopulmonary infections requiring IV antibiotics or hospitalization; **OR**
- Member meets both of the following:
  - Member has a history of multiple hard to treat infections as indicated by at least one of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent, deep skin or organ abscesses
    - Persistent thrush in the mouth or fungal infections on the skin
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The member has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

- Member is less than 18 years of age; **AND**
- Member has a diagnosis of Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) or Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet indication-specific relevant criteria identified in initial approval criteria; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- BUN and serum creatinine have been obtained within the last 6 months and the concentration and rate of infusion have been adjusted accordingly; **AND**

Primary Immunodeficiency (PID)

- Disease response as evidenced by one or more of the following:

- Decrease in the frequency of infection
- Decrease in the severity of infection

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP)

- Chronic ITP:
  - Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 10^9/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy

- Renewals will be authorized for members that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Multifocal Motor Neuropathy

- Renewals will be authorized for members that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Dermatomyositis

- Member had an improvement from baseline on physical exam and/or muscular strength and function

Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia (CLL)

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Continued treatment is necessary to decrease the risk of infection

Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

- Member has been re-evaluated by their physician.

QUANTITY LIMITS (1 BILLABLE UNIT = 500 MG FOR ALL CODES EXCEPT J1577, J1553 1 BILLABLE UNIT = 100 MG)

Primary Immunodeficiency (PID)

- 180 billable units per 21 days

Chronic Inflammatory Demyelinating Polyneuropathy:

- Load: 460 billable units per 5 days
- Maintenance: 230 billable units per 21 days

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP)

- 460 billable units per 28 days

Kawasaki's Disease

- 460 billable units for 2 doses only

Multifocal Motor Neuropathy

- 460 billable units per 28 days

Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia (CLL)

- 90 billable units per 21 days

Dermatomyositis

- 460 billable units per 28 days

Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

- 400 billable units per 2 days

LENGTH OF AUTHORIZATION

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Prior authorization validity will be provided initially for 1 month for the following indications:
    - Acute Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura
    - Kawasaki's Disease
  - Prior authorization validity will be provided initially for 3 months for the following indications:
    - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
    - Multifocal Motor Neuropathy
    - Dermatomyositis
    - Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)
- Renewal: Prior authorization validity may be renewed every 12 months thereafter, unless otherwise specified.
  - Renewal for Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) will be required every 3 months.
  - Prior authorization validity may NOT be renewed for the following indications:
    - Acute Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura
    - Kawasaki's Disease

*IVIG Products include: Asceniv™; Alyglo™; Bivigam®; Flebogamma®; Gamunex-C®; Gammagard® Liquid; Gammagard® S/D; Gammagard Liquid ERC®; Gammaked™; Gammaplex®; Octagam®; Privigen®; Panzyga®; Qivigy®; Yimmugo®

IXEMPRA® (IXABEPILONE)

HCPCS: J9207

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a history of a severe hypersensitivity to agents containing Cremophor® EL or its derivatives (e.g., polyoxyethylated castor oil); **AND**
- If used in combination with capecitabine, the member must not have an AST or ALT >2.5 x ULN or bilirubin >1 x ULN; **AND**
- Used for locally advanced or metastatic breast cancer; **AND**
  - Member has failed or is resistant to treatment with an anthracycline and a taxane OR member is taxane resistant and further anthracycline therapy is contraindicated; **AND**
    - Used in combination with capecitabine; **OR**
    - Used as a single agent after failure on capecitabine.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

90 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

IZERVAY™ (AVACINCAPTAD PEGOL)

HCPCS: J2782

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a baseline assessment for all the following: best corrected visual acuity (BCVA), fundus autofluorescence (FAF) imaging, and optical coherence tomography (OCT); **AND**
- Member is free of ocular and/or peri-ocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Will not be used in combination with other intravitreal complement inhibitor therapies; **AND**
- Member does not have category 5, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**
- Member has a diagnosis of Geographic Atrophy (GA) as defined by a phenotype of geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; **AND**
- Disease is secondary to age-related macular degeneration (AMD); **AND**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.); **AND**
- Member must have an inadequate response to an adequate trial of, or contraindication, or intolerance to Syfovre (pegcetacoplan).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

40 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

JELMYTO® (MITOMYCIN)

HCPCS: J9281

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a perforation of the bladder or upper urinary tract; **AND**
- Therapy will be used for pyelocalyceal instillation only; **AND**
- Used as a single agent; **AND**
- Member has low-grade upper tract urothelial cancer (LG-UTUC); **AND**
- Used as primary treatment; **AND**
- Member has at least one measurable tumor 5 to ≤ 15 mm.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

80 billable units every week for 6 weeks then 80 billable units every month for 11 months

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

JEMPERLI (DOSTARLIMAB-GXLY)

HCPCS: J9272

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified; **AND**
- Member meets indication specific criteria below:

Endometrial Cancer

- Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; **AND**
  - Member has primary advanced or recurrent disease.

Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer

- Member has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **AND**
- Used as a single agent; **AND**
  - Used as subsequent therapy for unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic disease; **AND**
    - Member has endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen in any setting; **OR**
    - Member has solid tumors that have progressed on or following prior treatment.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Endometrial Cancer

- 50 billable units every 21 days for 6 doses, then 100 billable units every 42 days

Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer

- 50 billable units every 21 days for 4 doses, then 100 billable units every 21 days for 5 doses then 100 billable units every 42 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

KADCYLA® (ADO-TRASTUZUMAB EMTANSINE)

HCPCS: J9354

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as a single agent; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive breast cancer as determined by an FDA-approved or CLIA-compliant test; **AND**
  - Used as adjuvant therapy; **AND**
    - Member has early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based therapy; **OR**
  - Member has metastatic or recurrent unresectable disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
    - Used as second-line therapy and beyond; **OR**
  - Member has metastatic disease that recurred during or within 6 months of completing adjuvant therapy; **AND**
    - Member previously received trastuzumab and a taxane, separately or in combination.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Left ventricular ejection fraction (LVEF) obtained within the previous 3 months as follows:
  - Metastatic or Recurrent Breast Cancer: LVEF is >45% OR LVEF is 40% to ≤45% and absolute decrease is <10% from baseline; **OR**
  - All other indications: LVEF is ≥50% OR LVEF is 45% to <50% and absolute decrease is <10% from baseline.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

480 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

KALBITOR® (ECALLANTIDE)

HCPCS: J1290

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used as monotherapy for treatment of acute hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

240 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

KANUMA® (SEBELIPASE ALFA)

HCPCS: J2840

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 month of age; **AND**
- Documented baseline values for one or more of the following have been obtained:
  - Weight-for-age z-scores for members exhibiting growth failure
  - Low-density lipoprotein cholesterol (LDL-c)
  - High-density lipoprotein cholesterol (HDL-c)
  - Non-HDL-c
  - Triglycerides
  - Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT); **AND**
- Diagnosis of lysosomal acid lipase (LAL) deficiency has been confirmed by either biallelic pathogenic variants in LIPA or deficient LAL enzyme activity in peripheral blood leukocytes, fibroblasts, or dried blood spots.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

340 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 16 months of age through 10 years of age; **AND**
- Member has a diagnosis of severe Aromatic L-amino acid decarboxylase (AADC) deficiency as established by the following:
  - Member has biallelic pathogenic variants in DDC gene identified by molecular genetic testing; **OR**
  - Member cerebrospinal fluid (CSF) or plasma neurotransmitter profile is consistent with AADC deficiency; **AND**
    - Member has significantly reduced AADC enzyme activity in plasma; **AND**
- Member is experiencing persistent neurological defects (e.g., autonomic dysfunction, hypotonia, dystonia and other movement disorders, etc.) secondary to AADC deficiency despite standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitor, pyridoxine, or other forms of vitamin B6) Note: patients should be on stable dosages for at least 3 months prior to treatment with eladocagene; **AND**
- Member is unable to ambulate independently; **AND**
- Member has achieved skull maturity as assessed by neuroimaging; **AND**
- Member does not have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency; **AND**
- Member has not received prior gene therapy; **AND**
- Member must not have a baseline anti-adeno-associated virus, serotype 2 (anti-AAV2) antibody titer above the established threshold for a positive result; **AND**
- Member does not have any contraindications that would preclude the surgical intraputaminal administration.

QUANTITY LIMITS

1 billable unit (1 dose of up to 1.8×10^{11} vector genomes) one time only

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal.

KEPIVANCE® (PALIFERMIN)

HCPCS: J2425

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Member has a hematologic malignancy (i.e., NHL, Hodgkin's disease, AML, ALL, CML, CLL, or MM); **AND**
- Member will be receiving an autologous hematopoietic stem cell transplant; **AND**
- Member will be receiving a preparative regimen which includes myelotoxic therapy predicted to result in ≥ WHO Grade 3 mucositis in the majority of members; **AND**
- Member will not receive melphalan 200 mg/m^2 as a conditioning regimen; **AND**
- Kepivance will not be administered within 24 hours before, during infusion of, or within 24 hours after administration of myelotoxic chemotherapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 50 MCG)

624 billable units every 14 days for 6 total doses

LENGTH OF AUTHORIZATION

3 months for initial approval, not eligible for renewal

KESIMPTA® (OFATUMUMAB)

HCPCS: J9302

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of dimethyl fumarate or a preferred injectable agent for multiple sclerosis on the PDL (see Multiple Sclerosis Agents on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

2 billable units at weeks 0, 1, and 2 then 2 billable units monthly starting at week 4

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

KEYTRUDA® (PEMBROLIZUMAB)

HCPCS: J9271

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1200 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

KEYTRUDA QLEX™ (PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH)

HCPCS: J9277

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Therapy will not be used concomitantly with intravenous pembrolizumab; **AND**
- Intravenous pembrolizumab must be used for members weighing < 55 kg.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

790 billable units every 6 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

KIMMTRAK® (TEBENTAFUSP-TEBN)

HCPCS: J9274

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has received the first three infusions (i.e., Day 1, 8, 15) in an appropriate healthcare setting and did not experience Grade 2 or worse hypotension (i.e., hypotension requiring medical intervention); **AND**
- Member does not have a clinically significant cardiac disease or impaired cardiac function (i.e., congestive heart failure [NYHA grade ≥ 2], uncontrolled hypertension or clinically significant arrhythmia requiring medical treatment, QT interval > 470 msec or congenital long QT syndrome, acute myocardial infarction or unstable angina pectoris < 6 months prior to start of therapy); **AND**
- Member does not have symptomatic or untreated brain metastases; **AND**
- Member has unresectable or metastatic Uveal Melanoma; **AND**
- Member has HLA-A*02:01 genotype positive disease as determined by FDA approved or CLIA compliant test.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

400 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

KISUNLA™ (DONANEMAB-AZBT)

HCPCS: J0175

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing at least ONE objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13/14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], Montreal Cognitive Assessment (MoCA), etc.); **AND**
- Member does not have any of the following risk factors for intracerebral hemorrhage: findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage > 1 cm in greatest diameter, >4 microhemorrhages, superficial siderosis, vasogenic edema); **AND**
- Members receiving antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) prior to starting treatment with Kisunla have been on a stable dose for at least 4 weeks; **AND**
  - Member has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier) and the prescriber has informed the member that those who are homozygotes have a higher incidence of developing Amyloid-Related Imaging Abnormalities (ARIA); **OR**
  - Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygotes and, therefore, if they are at higher risk for developing ARIA; **AND**
- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Member has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment and periodically throughout therapy; **AND**
- Will not be used concurrently with other anti-amyloid immunotherapies (i.e., lecanemab IV/SQ, etc.); **AND**
- Member has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer’s Disease (AD) or has mild Alzheimer’s dementia AND both of the following:
  - Positron Emission Tomography (PET) scan positive for amyloid beta plaque or cerebrospinal fluid (CSF) assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42; **AND**
  - One of the following*:
    - Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of at least 0.5; **OR**
    - Mini-Mental Status Exam (MMSE) score between 20-28, inclusive; **OR**
    - Montreal Cognitive Assessment (MoCA) score 18-25, inclusive; **AND**
- Other conditions mimicking, but of non-Alzheimer’s Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member has not progressed to moderate or severe AD; **AND**
- Member has received a pre- 2nd, 3rd, 4th, AND 7th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities-hemosiderin (ARIA-H) microhemorrhages.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

- Infusion 1: 175 billable units
- Infusion 2: 350 billable units
- Infusion 3: 525 billable units
- Infusion 4 and beyond: 700 billable units every four weeks thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

KORSUVA® (DIFELIKEFALIN)

HCPCS: J0879

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Documented baseline score from an objective clinical evaluation tool, such as: Worst Itching Intensity Numerical Rating Scale (WI-NRS), etc.; **AND**
- Other underlying causes of pruritus have been considered and addressed (i.e., sub-optimal dialysis Kt/V targets, hyperparathyroidism, hyperphosphatemia, hypercalcemia, and xerosis); **AND**
- Member has moderate to severe pruritus; **AND**
- Member is undergoing hemodialysis (Note: Excludes use in patients on peritoneal dialysis).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MCG)

1950 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

KRYSTEXXA® (PEGLOTICASE)

HCPCS: J2507

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member must not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (Note: Members at increased risk for G6PD deficiency [e.g., patients of African, Mediterranean, Southern European, Middle Eastern, and Southern Asian ancestry] have been screened prior to starting treatment); **AND**
- Documentation of baseline serum uric acid level ≥ 7 mg/dL (current lab reports are required for renewal); **AND**
- Therapy will not be given in combination with other urate lowering therapies such as allopurinol, febuxostat, probenecid, etc.; **AND**
- Documented contraindication, intolerance, or clinical failure (i.e., inability to reduce serum uric acid to < 6 mg/dL) during a minimum (3) month trial on previous therapy with maximum tolerated dose of xanthine oxidase inhibitors (e.g., allopurinol or febuxostat) or uricosuric agents (e.g., probenecid, etc.); **AND**
- Used in combination with methotrexate OR as a single agent if methotrexate is contraindicated or not clinically appropriate; **AND**
- Member has one of the following:
  - Two or more gout flares per year that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDS), or oral or injectable corticosteroids; **OR**
  - At least one (1) non-resolving subcutaneous tophi; **OR**
  - Evidence of radiographic damage of any modality that is attributable to gout.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

16 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

KYMRIAH® (TISAGENLECLEUCEL)

HCPCS: Q2042

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have an active infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during tisagenlecleucel treatment and until immune recovery following treatment; **AND**
- Member will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Member has not received prior CAR-T therapy; **AND**
- Member has not received other anti-CD19 therapy (e.g., blinatumomab, tafasitamab, loncastuximab tesirine) or member previously received other anti-CD19 therapy and rebiopsy indicates CD19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with tisagenlecleucel; **AND**
- Member meets indication specific criteria below:

Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

- Member is 18 to 25 years of age; **AND**
  - Member has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Disease is refractory or in second or later relapse; **AND**
    - Used following therapy that has included two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, ponatinib, nilotinib, or bosutinib); **OR**
  - Member has Philadelphia chromosome (Ph)-negative disease; **AND**
    - Disease is refractory or in second or later relapse

Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia

- Member is 2 to 17 years of age; **AND**
  - Member has BCR: ABL1-positive disease; **AND**
    - Disease is tyrosine kinase inhibitor (TKI) intolerant or refractory; **OR**
    - Member has relapsed disease post-hematopoietic stem cell transplant (HSCT); **OR**
  - Member has BCR: ABL1-negative disease; **AND**
    - Disease is refractory or in second or later relapse

B-Cell Lymphomas

- Member is at least 18 years of age; **AND**
- Member does not have primary central nervous system lymphoma; **AND**
  - Member has follicular lymphoma; **AND**
    - Member has received at least two (2) prior lines of systemic therapy; **AND**
    - Member has relapsed or refractory disease; **OR**
  - Member has large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma; **AND**
    - Member has received at least two (2) prior lines of therapy; **AND**
    - Member has relapsed or refractory disease

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 infusion of up to 600 million CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

KYPROLIS® (CARFILZOMIB)

HCPCS: J9047

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used for relapsed, progressive, or refractory multiple myeloma after one to three lines of previous therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with one of the following regimens:
    - Dexamethasone with or without lenalidomide
    - Dexamethasone and daratumumab/daratumumab and hyaluronidase
    - Dexamethasone and isatuximab.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

720 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

LAMZEDE® (VELMANASE ALFA-TYCV)

HCPCS: J0217

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 3 years of age; **AND**
- Documented baseline serum oligosaccharides; **AND**
- Documented baseline age-appropriate values for one or more of the following have been obtained: 6-minute walk test (6-MWT), 3-minute stair climb test (3-MSCT), pulmonary function tests (e.g., forced vital capacity), motor function [i.e., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)], etc. (Note: For very young members in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis); **AND**
- Females of reproductive potential have a confirmed negative pregnancy test prior to initiating treatment; **AND**
- Therapy is used to treat non-central nervous system manifestations of alpha mannosidosis (i.e., skeletal abnormalities, myopathy, motor function disturbances, immunodeficiency, etc.); **AND**
- Member has a definitive diagnosis of alpha mannosidosis as confirmed by ONE of the following:
  - Identification of deficient acid alpha-mannosidase enzyme activity in peripheral blood leukocytes or other nucleated cells such as fibroblasts of <11% of normal activity; **OR**
  - Identification of biallelic pathogenic variants in MAN2B1 by molecular genetic testing.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

440 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

LEMTRADA® (ALEMTUZUMAB)

HCPCS: J0202

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment; **AND**
- Member has a baseline electrocardiogram (ECG); **AND**
- Member does not have human immunodeficiency virus (HIV) infection; **AND**
- Member has been evaluated and screened for the presence of tuberculosis (TB) prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Member does not have an active infection; **AND**
- Provider will confirm that member will not receive live vaccines while on therapy or within 6 weeks prior to initiation of treatment; **AND**
- Member has received a baseline skin exam for melanoma and will receive yearly skin exams while on therapy; **AND**
- Member has a baseline urine protein to creatinine ratio AND thyroid-stimulating hormone (TSH) level prior to initiation of treatment and will receive ongoing laboratory monitoring during treatment; **AND**
- Member will receive anti-viral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is ≥ 200 cells/µL); **AND**
- Member has been diagnosed with a relapsing form of multiple sclerosis [i.e., relapsing-remitting disease (RRMS) or active secondary progressive MS (SPMS)]; **AND**
- Member must have a confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Used as single agent therapy; **AND**
- Member must have had an inadequate response to an adequate trial of two or more drugs indicated for the treatment of MS; **AND**
- Will not be used for the treatment of clinically isolated syndrome (CIS).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- First Course: 12 billable units daily for 5 days during the first 12 months
- Subsequent Courses: 12 billable units daily for 3 days every 12 months thereafter

LENGTH OF AUTHORIZATION

5 doses in the first 12 months for initial approval, 3 doses every 12 months for renewal

LENMELDY™ (ATIDARSAGENE AUTOTEMCEL)

HCPCS: J3391

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is less than 18 years of age; **AND**
- Member will be screened and found to be negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), and mycoplasma infection before collection of cells for manufacturing; **AND**
- Member will not be administered vaccinations during the 6 weeks preceding the start of myeloablative conditioning, and until hematological recovery following treatment (Note: Where feasible, administer childhood vaccinations prior to myeloablative conditioning); **AND**
- Member risk factors for thrombosis as well as veno-occlusive disease have been evaluated prior to administration; **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Member will be monitored for hematological malignancies periodically after treatment; **AND**
- Member will not receive prophylactic HIV anti-retroviral therapy for at least one-month preceding mobilization; **AND**
- Member will have mobilization of stem cells using granulocyte-colony stimulating factor (G-CSF with or without plerixafor); **AND**
- Used as single agent therapy (Note: not inclusive of busulfan conditioning regimen); **AND**
- Member has not received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function); **AND**
- Member does not have a known and available suitable 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic HSCT; **AND**
- Member has not received other gene therapy for MLD; **AND**
- Member has a confirmed diagnosis of MLD (also known as arylsulfatase A deficiency) as evidenced by the following biochemical and molecular markers:
  - Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood leukocytes or fibroblasts OR increased urinary excretion of sulfatides; **AND**
  - Presence of biallelic ARSA pathogenic mutation of known or novel polymorphisms (Note: For members with novel mutation(s), a 24-hour urine collection must show elevated sulfatide levels); **AND**
- Member has pre-symptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) disease (Note: Requests for children with late juvenile form of the disease will be reviewed on a case-by-case basis).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit for one dose

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

LEQEMBI® (LECANEMAB-IRMB)

HCPCS: J0174

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Member has a diagnosis of mild cognitive impairment (MCI) due to AD or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) AND both of the following:
  - Positron Emission Tomography (PET) scan positive for amyloid beta plaque or CSF assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42; **AND**
  - One of the following*:
    - Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of at least 0.5; **OR**
    - MMSE score between 20-28, inclusive; **OR**
    - Montreal Cognitive Assessment (MoCA) score 18-25, inclusive; **AND**
- Other conditions mimicking, but of non-Alzheimer's Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.); **AND**
- Member is at least 18 years of age; **AND**
- Member has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment and periodically throughout therapy; **AND**
- Member does not have any of the following risk factors for intracerebral hemorrhage: findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage greater than 1 cm in greatest diameter, greater than 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage; **AND**
- Members receiving antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) prior to starting treatment with Leqembi have been on a stable dose for at least 4 weeks; **AND**
  - Member has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier) and the prescriber has informed the member that those who are homozygotes have a higher incidence of developing ARIA; **OR**
  - Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygotes and, therefore, if they are at higher risk for developing ARIA.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1200 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

LEQVIO® (INCLISIRAN)

HCPCS: J1306

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Therapy is prescribed by or in consultation with a specialist (cardiologist, lipidologist, endocrinologist); **AND**
- Member has prior treatment history with highest available dose or maximally tolerated dose of high intensity statin (atorvastatin or rosuvastatin) and ezetimibe for at least three continuous months with failure to reach target LDL-C (i.e., extremely high risk atherosclerotic cardiovascular disease [ASCVD] members with LDL-C ≥ 70 mg/dL, very high risk ASCVD members with LDL-C ≥ 100 mg/dL, and high-risk ASCVD members with LDL-C ≥ 130 mg/dL); **AND**
- Maximally tolerated statin will continue to be used with inclisiran; **OR**
  - If the member is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
    - Muscle symptoms resolve after discontinuation of statin; **AND**
    - Muscle symptoms occurred when rechallenged at a lower dose of the same statin; **AND**
    - Muscle symptoms occurred after switching to an alternative statin; **AND**
    - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
  - The member has been diagnosed with statin-induced rhabdomyolysis; **AND**
- Product is being used for of one of the following indications:
  - In adult members, as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of members with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C); **OR**
  - In adult and pediatric members aged 12 years and older with heterozygous familial hypercholesterolemia [HeFH] to reduce low-density lipoprotein cholesterol (LDL-C); **AND**
    - Diagnosis is confirmed as defined by the Dutch Lipid Clinic Network criteria (total score greater than 5) or Simon Broome diagnostic criteria; **OR**
  - In adult and pediatric members aged 12 years and older as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in members with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C; **AND**
    - Diagnosis is confirmed by genetic testing confirming the presence of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus; **OR**
    - Diagnosis is confirmed by any of the following:
      - Untreated LDL-C > 400 mg/dL and cutaneous or tendon xanthoma before age 10 years

- Untreated LDL-C > 400 mg/dL and untreated elevated LDL-C levels consistent with homozygous familial hypercholesterolemia in one parent
- Treated LDL-C ≥ 300 mg/dL and cutaneous or tendon xanthoma before age 10 years
- Treated LDL-C ≥ 300 mg/dL and untreated elevated LDL-C levels consistent with homozygous familial hypercholesterolemia in one parent

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has achieved at least a 30% reduction in LDL-C since the beginning of treatment and continues to benefit from therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

284 billable units at months 0, 3 and then every 6 months

LENGTH OF AUTHORIZATION

3 months for initial approval, 6 months for renewal

LEUKINE® (SARGRAMOSTIM)

HCPCS: J2820

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 50 MCG)

Acute Radiation Syndrome

- 420 billable units every 28 days

Neuroblastoma

- 350 billable units every 14 days

All other indications

- 210 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

LEUPROLIDE DEPOT SUSPENSION

HCPCS: J1950, J1951, J1952, J1954, J9003, J9217

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member meets indication and HCPCS specific criteria below:

Central Precocious Puberty (CPP) (J1950 and J1951)

- Member is less than 13 years of age; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native growth hormone-releasing hormone (GnRH); **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**
- Will not be used in combination with growth hormone.

Endometriosis (J1950)

- Member's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment).

Uterine Leiomyomata (fibroids) (J1950)

- Member's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
- Member is receiving iron therapy.

Prostate Cancer (J9217, J1952, J1954)

- Member has a diagnosis of Prostate Cancer.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member meets indication specific renewal criteria below:

Endometriosis

- Member has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
- Member continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
- Member will have bone density assessment prior to retreatment; **AND**

- Extended GnRH-agonist treatment will be used in combination with norethindrone add-back therapy.

QUANTITY LIMITS

J1950 (1 billable unit = 3.75 mg)

- Endometriosis, Uterine Leiomyomata (fibroids): 3 billable units every 84 days
- Central Precocious Puberty (CPP): 24 billable units every 168 days

J1951 (1 billable unit = 0.25 mg)

- Central Precocious Puberty (CPP): 180 billable units every 168 days

J1952 (1 billable unit = 1 mg)

- Prostate Cancer: 42 billable units every 168 days

J1954 (1 billable unit = 7.5 mg)

- Prostate Cancer: 3 billable units every 84 days

J9217 (1 billable unit = 7.5 mg)

- Prostate Cancer: 12 billable units every 336 days

J9003 (1 billable unit = 1 mg)

- Prostate Cancer: 21 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

LIBTAYO® (CEMIPLIMAB-RWLC)

HCPCS: J9119

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Medication is prescribed by or in consultation with an oncologist; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy; **AND**
- Member meets indication specific criteria below:

Cutaneous Squamous Cell Carcinoma (cSCC)

- Used as a single agent; **AND**
- Member has metastatic, locally advanced, or recurrent disease; **AND**
  - Member is not a candidate for curative surgery or curative radiation therapy; **OR**
- Used as adjuvant therapy; **AND**
  - Member has a high risk of recurrence after surgery and radiation; **OR**
- Used as neoadjuvant therapy; **AND**
  - Member has borderline resectable disease, unresectable disease, or surgery may carry a high morbidity; **OR**
  - Used for one of the following:
    - Tumor has very rapid growth
    - In-transit metastasis
    - Lymphovascular invasion
    - Surgery alone may not be curative or may result in significant functional limitation; **AND**
  - Member has very high-risk disease*; **OR**
  - Member has locally advanced disease

*Very High-Risk features include preoperative clinical tumor diameter > 4 cm, poor differentiation, desmoplastic disease, thickness or level of invasion is > 6 mm or invasion beyond subcutaneous fat, tumor cells within the nerve sheath of a nerve lying deeper than the dermis or measuring ≥ 0.1 mm, lymphatic or vascular involvement

Basal Cell Carcinoma (BCC)

- Used as a single agent; **AND**
  - Member has locally advanced or metastatic disease; **OR**
  - Member has nodal disease and surgery is not feasible

Non-Small Cell Lung Cancer (NSCLC)

- Member has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**

- Used in combination with platinum-based chemotherapy (e.g., paclitaxel and either carboplatin or cisplatin or pemetrexed and either carboplatin or cisplatin); **AND**
  - Used as first-line therapy for one of the following:
    - Members who have tumors that are negative for actionable molecular biomarkers* ¥
    - Members who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **OR**
  - Used as subsequent therapy for one of the following:
    - Members who are positive for one of the following molecular biomarkers and have received prior targeted therapy: EGFR S768I, L861Q, and/or G719X
    - Members who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping; **OR**
- Used in combination with pemetrexed; **AND**
  - Used as continuation maintenance therapy in members who have achieved a tumor response or stable disease after first-line therapy with cemiplimab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; **OR**
- Used as a single agent; **AND**
  - Member has tumors that are negative for actionable molecular biomarkers* ¥ and high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA approved or CLIA compliant test; **AND**
    - Used as first-line therapy; **OR**
    - Used as continuation maintenance therapy in members who achieved a tumor response or stable disease after first-line therapy with cemiplimab as monotherapy or as part of combination therapy; **OR**
  - Member has tumors with PD-L1 expression < 1% or ≥ 1%–49%; **AND**
    - Used as continuation maintenance therapy in members who have achieved a tumor response or stable disease following initial therapy with cemiplimab combination therapy

* **Note**: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these members are treated as though they do not have driver oncogenes.

¥ **Note**: May also be used for members with KRAS G12C mutation positive tumors.

RENEWAL CRITERIA

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, identified above; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis,

colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, and dermatologic adverse reactions), complications of allogeneic hematopoietic stem cell transplantation (HSCT); **AND**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

700 billable units every 42 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal*

- *Neoadjuvant therapy for Cutaneous Squamous Cell Carcinoma (cSCC): Prior authorization validity may not be renewed.
- *Adjuvant therapy for cSCC: Prior authorization validity may be renewed up to a maximum of 48 weeks of total therapy.
- *Metastatic, locally advanced, or recurrent cSCC, and Basal Cell Carcinoma (BCC): Prior authorization validity may be renewed up to a maximum of twenty-four (24) months of therapy (35 doses)

LOQTORZI® (TORIPALIMAB-TPZI)

HCPCS: J3263

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy; **AND**
- Member has Nasopharyngeal Carcinoma (NPC); **AND**
  - Used as first-line therapy; **AND**
    - Member has metastatic or recurrent, locally advanced disease; **AND**
    - Used in combination with cisplatin and gemcitabine; **OR**
  - Used as subsequent therapy; **AND**
    - Member has recurrent unresectable or metastatic disease; **AND**
      - Used as single-agent therapy; **AND**
        - Member experienced disease progression on or after a platinum-containing chemotherapy regimen.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

480 billable units every 2 weeks

LENGTH OF AUTHORIZATION

- 6 months for initial approval, 6 months for renewal
- For first-line treatment of NPC with cisplatin and gemcitabine: renewal every 6 months up to a maximum of 24 months (35 total doses)

LUMIZYME® (ALGLUCOSIDASE ALFA)

HCPCS: J0221

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Documented baseline age-appropriate values for one or more of the following:
  - Infantile-onset disease: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6-MWT); **OR**
  - Late-onset (non-infantile) disease: FVC and/or 6-MWT; **AND**
- Will not be used in combination with other enzyme replacement therapies; **AND**
- Members susceptible to fluid volume overload or those with an acute underlying respiratory illness or compromised cardiac or respiratory function will be closely monitored for exacerbation of their cardiac or respiratory status during infusion; **AND**
- Member has a diagnosis of Pompe Disease (Acid Alpha-Glucosidase [GAA] deficiency).

NOTE: For very young members in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member is being monitored for antibody formation (including neutralizing antibodies).

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

230 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

LUNSUMIO™ (MOSUNETUZUMAB-AXGB) AND LUNSUMIO VELO™ (MOSUNETUZUMAB-AXGB)

HCPCS: J9350

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Member does not have central nervous system (CNS) lymphoma; **AND**
- Used as single agent therapy; **AND**
- Member will not use subcutaneous and intravenous mosunetuzumab concomitantly; **AND**
- Member has follicular lymphoma; **AND**
  - Used for histologically confirmed grade 1-3a disease (classic follicular lymphoma); **AND**
  - Member has relapsed or refractory disease; **AND**
  - Used after at least two prior lines of systemic therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

63 billable units every 21 days

LENGTH OF AUTHORIZATION

168 days (eight 21-day cycles) for initial approval, 189 days (nine 21-day cycles) for renewal

LUXTURNA® (VORETIGENE NEPARVOVEC-RZYL)

HCPCS: J3398

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 12 months of age; **AND**
- Member must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene; **AND**
- Member has not had intraocular surgery within six months; **AND**
- Member has not previously received subretinal administration of a gene therapy vector, or Luxturna, into the intended eye; **AND**
- Member has a definitive diagnosis confirming biallelic RPE65 mutation-associated retinal dystrophy; **AND**
- Member must have viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating one or more of the following:
  - An area of retina within the posterior pole of > 100 µm thickness shown on OCT
  - ≥ 3-disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
  - Remaining visual field within 30 degrees of fixation as measured by an III4e isopter or equivalent.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 BILLION VECTOR GENOMES)

150 billable units per eye

LENGTH OF AUTHORIZATION

One dose per eye, not eligible for renewal

LYFGENIA™ (LOVOTIBEGLOGENE AUTOTEMCEL)

HCPCS: J3394

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a documented medical diagnosis of SCD by either confirmatory genetic testing or hemoglobin fractionation; **AND**
- Member is at least 12 years of age at the expected time of gene therapy administration; **AND**
- Failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per healthcare professional judgement) at any point in the past; **AND**
- CGT Product is prescribed by or in consultation with a board-certified hematologist with SCD expertise; **AND**
- CGT Product will be administered in a qualified treatment center; **AND**
- Either a or b (based on provider attestation):
  a. Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); **OR**
  b. Experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the Eligible Beneficiary's treating clinician.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

A single dose of Lyfgenia containing a minimum of 3.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

LYMPHIR™ (DENILEUKIN DIFTITOX-CXDL)

HCPCS: J9161

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member's serum albumin is greater than or equal to 3 g/dL; **AND**
- Member will be regularly assessed for signs and symptoms of capillary leak syndrome (e.g., more than one of the following: hypotension, edema, serum albumin <3 g/dL); **AND**
- Member will have an ophthalmic examination at baseline and periodically throughout therapy as clinically indicated; **AND**
- Used as single agent systemic therapy; **AND**
- Member has a diagnosis of Cutaneous T-Cell Lymphoma (CTCL) - Mycosis Fungoides/Sezary Syndrome; **AND**
  - Used as primary systemic therapy; **AND**
    - Member has stage IB-III mycosis fungoides; **OR**
  - Used as subsequent therapy after at least one prior systemic therapy; **AND**
    - Member has stage I, II, or III disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

6000 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

LYNOZYFIC™ (LINVOSELTAMAB-GCPT)

HCPCS: J9601

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of all step-up doses; **AND**
- Member had an absence of unacceptable toxicity while on inpatient administration; **AND**
- Member will be administered prophylaxis for infection (e.g., antimicrobials, antibiotics, antifungals, antivirals, vaccines, and subcutaneous or intravenous immunoglobulin (IVIG)) according to local guidelines; **AND**
- Member immunoglobulin levels will be monitored prior to and during therapy and treated appropriately; **AND**
- Member does not have active CNS involvement or clinical signs of meningeal involvement from multiple myeloma; **AND**
- Member has not had an allogeneic stem cell transplant or an autologous stem cell transplant within the previous 12 weeks; **AND**
- Member has relapsed or refractory multiple myeloma; **AND**
- Used as a single agent; **AND**
- Member has received at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

200 billable units every week

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

MEPSEVII™ (VESTRONIDASE ALFA-VJBK)

HCPCS: J3397

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 5 months of age; **AND**
- Documented baseline age-appropriate values for one or more of the following have been obtained: 6-minute walk test (6-MWT), motor function (i.e., Bruininks-Oseretsky Test of Motor Proficiency [BOT-2]), liver and/or spleen volume, urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, skeletal involvement (i.e., Z-score), pulmonary function tests, shoulder flexion, visual acuity (**Note**: for very young patients in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis); **AND**
- Therapy is being used to treat non-central nervous system manifestations of the disease and member does not have severe, irreversible cognitive impairment (***Note**: Requests for continued therapy in patients with severe, irreversible cognitive impairment will be reviewed on a case-by case basis); **AND**
- Member has a definitive diagnosis of mucopolysaccharidosis VII (MPS VII) as confirmed by BOTH of the following:
  - Beta-glucuronidase enzyme deficiency in peripheral blood leukocytes, fibroblasts, or dried blood spots; **AND**
  - Detection of pathogenic mutations in the GUSB gene by molecular genetic testing.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

460 billable units (460 mg) every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

MONJUVI® (TAFASITAMAB-CXIX)

HCPCS: J9349

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received prior therapy with immunomodulatory imide (IMiD-class) agents; **AND**
- Member has not received prior therapy with CD19-directed therapy OR previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Member has follicular lymphoma; **AND**
  - Used as subsequent therapy for no response, relapsed, refractory, or progressive disease; **AND**
  - Member does NOT have a relapsed or refractory marginal zone lymphoma; **AND**
  - Member has received at least one prior systemic therapy including an anti-CD20 monoclonal antibody; **AND**
  - Used in combination with lenalidomide and rituximab; **OR**
- Member has diffuse large B-cell lymphoma (DLBCL) (including DLBCL not otherwise specified and DLBCL arising from low grade lymphoma); **AND**
  - Used as subsequent therapy in combination with lenalidomide; **AND**
    - Used for relapsed or refractory disease in members who are not eligible for autologous stem cell transplant (ASCT).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

3500 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

MYLOTARG™ (GEMTUZUMAB OZOGAMICIN)

HCPCS: J9203

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not previously received gemtuzumab ozogamicin; **AND**
- Baseline electrocardiogram (ECG) has been obtained in members with a history of or predisposition for QTc prolongation; **AND**
- Member has CD33-positive disease; **AND**
- Member has a diagnosis of Acute Myeloid Leukemia (AML); **AND**
  - Member has newly-diagnosed disease; **AND**
    - Used in combination with daunorubicin and cytarabine; **AND**
      - Member is at least 1 month of age; **OR**
    - Used as a single agent; **AND**
      - Member is at least 18 years of age; **OR**
  - Member has relapsed or refractory disease; **AND**
    - Used as a single agent; **AND**
      - Member is at least 2 years of age.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

315 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

MYOBLOC® (RIMABOTULINUMTOXINB)

HCPCS: J0587

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have any of the following:
  - Hypersensitivity to any botulinum toxin product
  - Active infection at the proposed injection site
  - Any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**
- Member meets indication specific criteria below:

Cervical Dystonia

- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck.

Chronic Sialorrhea

- Member has a history of troublesome sialorrhea for at least a 3-month period.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 100 UNITS)

100 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NAGLAZYME® (GALSULFASE)

HCPCS: J1458

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Documented baseline 12-minute walk test (12-MWT), 3-minute stair climb test (3-MSCT), and/or pulmonary function tests (e.g., FEV1, etc.); **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG); **AND**
- Therapy is being used to treat non-central nervous system manifestations of the disease and member does not have severe, irreversible cognitive impairment; **AND**
- Member has a definitive diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome) as confirmed by the following:
  - Detection of pathogenic mutations in the ARSB gene by molecular genetic testing; **OR**
  - Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes; **AND**
    - Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency [MSD]); **AND**
    - Member has an elevated urinary glycosaminoglycan (uGAG) level (i.e., dermatan sulfate or chondroitin sulfate) defined as being above the upper limit of normal by the reference laboratory.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

115 billable units every 7 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

NEULASTA® (PEGFILGRASTIM)

HCPCS: J2506

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)

HCPCS: J0219

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Member has documented baseline values for percent predicted forced vital capacity (FVC) and/or 6-minute walk test (6MWT) (Note: For very young patients in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis); **AND**
- Will not be used in combination with other enzyme replacement therapies; **AND**
- Members susceptible to fluid volume overload or those with an acute underlying respiratory illness or compromised cardiac or respiratory function, will be closely monitored for exacerbation of their cardiac or respiratory status during infusion; **AND**
- Member has a diagnosis of Pompe Disease (Acid Alpha-Glucosidase [GAA] deficiency) as confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase (GAA) enzyme activity; **OR**
  - Detection of biallelic pathogenic variants in the GAA gene by molecular genetic testing; **AND**
- Member has a diagnosis of late-onset (non-infantile) disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 4 MG)

575 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

NIKTIMVO™ (AXATILIMAB-CSFR)

HCPCS: J9038

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member weighs at least 40 kg; **AND**
- Member has recurrent or refractory chronic graft versus host disease (cGVHD); **AND**
- Used as a single agent or in conjunction with systemic steroids, calcineurin inhibitors (e.g., cyclosporin, etc.) or mTOR inhibitors (e.g., sirolimus, everolimus, etc.); **AND**
- Member is post-allogeneic stem cell transplant; **AND**
- Member has failed two or more previous lines of systemic therapy for the treatment of cGVHD.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

360 billable units every 2 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

NIVESTYM® (FILGRASTIM-AAFI)

HCPCS: Q5110

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

1560 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NPLATE® (ROMIPLOSTIM)

HCPCS: J2802

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is not on concurrent treatment with any other thrombopoietin receptor agonist or mimetic or fostamatinib; **AND**
- Romiplostim is not being used to attempt to normalize platelet count (i.e., use is limited to decreasing the risk of bleeding from thrombocytopenia by increasing platelet levels and not normalizing them); **AND**
- Laboratory values for platelet count are current (i.e., drawn within the previous 28 days, **note**: does not apply to patients receiving treatment for Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS]); **AND**
- Member meets indication specific criteria below:

Immune (idiopathic) Thrombocytopenia (ITP)

- The member is at increased risk for bleeding as indicated by platelet count less than 30 × 10^9/L (30,000/mm³); **AND**
  - Member has acute ITP; **AND**
    - Member is at least 18 years of age; **AND**
    - Member has previously failed any of the following treatments for ITP:
      - Corticosteroids; **OR**
      - Immunoglobulins; **OR**
      - Splenectomy; **OR**
  - Member has had chronic ITP for at least 6 months; **AND**
    - Member is at least 1 year of age; **AND**
    - Member has previously failed any of the following treatments for ITP:
      - Corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
      - Immunoglobulins; **OR**
      - Splenectomy

Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

- Member has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

Immune Thrombocytopenia

- 1250 billable units weekly

Hematopoietic Syndrome of Acute Radiation Syndrome

- 1250 billable units x 1 dose

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal* (*coverage for use to treat Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) may not be renewed

NUCALA (MEPOLIZUMAB)

HCPCS: J2182

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

Severe Asthma

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Member has asthma with an eosinophilic phenotype defined as blood eosinophils equal to or greater than150 cells/µL; **AND**
- Nucala will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Nucala will be used as add-on maintenance treatment in members regularly receiving both of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1); **AND**
- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

Eosinophil granulomatosis with polyangiitis (EGPA)

- Member is at least 18 years of age; **AND**
- Member has a confirmed diagnosis of EGPA§ (aka Churg-Strauss Syndrome); **AND**
- Nucala will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member has a baseline blood eosinophil count greater than or equal to 1000 cells/µL or greater than or equal to 10% eosinophils on white blood cell differential count; **AND**
- Member has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses); **AND**

- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

Hypereosinophilic syndrome (HES)

- Member is at least 12 years of age; **AND**
- Member has been diagnosed with HES (without an identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1- PDGFRα kinase-positive HES) for at least 6 months prior to starting treatment; **AND**
- Nucala will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member has a history of two or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
- Nucala will be used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy; **AND**
- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- Member is at least 18 years of age; **AND**
- Member has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Nucala will not be coadministered with another monoclonal antibody (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member has failed an 8-week trial of intranasal corticosteroid therapy; **AND**
- Nucala will be used in combination with intranasal corticosteroids unless unable to tolerate or is contraindicated; **AND**
- Member has tried and failed two preferred agents listed on the PDL where applicable for the requested product's intended use.

Inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of COPD with moderate to very severe airflow limitation, as defined by FEV1/FVC ratio < 0.7 and post-bronchodilator FEV1 of 20% to 80% predicted; **AND**
- Member has a peripheral blood eosinophil count ≥ 150 cells/μL at screening or ≥ 300 cells/μL in the year prior; **AND**
- Therapy will be used for add-on maintenance treatment in members regularly receiving background triple inhaled therapies (i.e., ICS, long-acting beta agonist, and long-acting muscarinic antagonist) unless otherwise contraindicated; **AND**

- Member has had at least 2 moderate (requiring treatment with oral/systemic corticosteroids and/or antibiotics) or 1 severe (requiring inpatient hospitalization) COPD exacerbation in the previous year, despite receiving triple inhaled therapy; **AND**
- Member has tried and failed an adequate trial of Dupixent, unless contraindicated or clinically inappropriate (i.e., cannot use Dupixent if blood eosinophil count is < 300 cells/μL at screening).

RENEWAL CRITERIA

Severe Asthma

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1).

Eosinophil granulomatosis with polyangiitis (EGPA)

- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
  - Member is in remission (defined as a Birmingham Vasculitis Activity Score [BVAS] score of 0 and a prednisone/prednisolone daily dose of ≤ 4 mg)
  - Decrease in maintenance dose of systemic corticosteroids
  - Improvement in BVAS score compared to baseline
  - Improvement in asthma symptoms or asthma exacerbations
  - Improvement in duration of remission or decrease in the rate of relapses.

Hypereosinophilic syndrome (HES)

- Member has had a disease response as indicated by a decrease in HES flares from baseline. Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least two occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sinonasal outcome test-22 [SNOT-22]); **OR**
- Member has improvement in at least one of the following response criteria:
  - Reduction in nasal polyp size
  - Reduction in need for systemic corticosteroids
  - Improvement in quality of life
  - Improvement in sense of smell

- Reduction of impact of comorbidities

Inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

- Member has experienced a disease response as indicated by improvement in COPD symptoms or COPD exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Use of antibiotics
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Severe Asthma, Inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, Chronic rhinosinusitis with nasal polyps (CRSwNP)

- 100 billable units every 28 days

Eosinophil granulomatosis with polyangiitis (EGPA), Hypereosinophilic syndrome (HES)

- 300 billable units every 28 days

Definitions

*** Components of severity for classifying asthma as severe may include any of the following (not all-inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

§ Eosinophilic Granulomatosis Polyangiitis (EGPA) Is defined as all of the following:

- History or presence of asthma
- Blood eosinophil level greater than 10% or an absolute count greater than 1000 cells/mm^3
- Two or more of the following criteria:
  - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates

- Sinonasal abnormalities
- Cardiomyopathy
- Glomerulonephritis
- Alveolar hemorrhage
- Palpable purpura
- Antineutrophil Cytoplasmic Antibody (ANCA) positivity

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NULIBRY® (FOSDENOPTERIN)

HCPCS: J1809

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Will not be used in combination with other substrate replacement therapy (e.g., recombinant cyclic pyranopterin monophosphate, etc.); **AND**
- Must be prescribed by, or in consultation with, a specialist in medical genetics or pediatric neurology; **AND**
- Member meets one of the following scenarios:
  - Member has a diagnosis of Molybdenum Cofactor Deficiency Type A (MoCD Type A) confirmed by a mutation in the MOCS1 gene suggestive of disease as identified on molecular genetic testing; **OR**
  - Member has biochemical features suggestive of MoCD Type A (i.e., elevated sulfites in urine, low serum uric acid, elevated urinary xanthine and hypoxanthine) and will be treated presumptively while awaiting genetic confirmation; **AND**
- Member has a baseline value for the following:
  - Urinary s-sulfocysteine (SSC) normalized to creatinine; **AND**
  - Clinical notes regarding signs and symptoms of disease which may include, but are not limited to, seizure frequency/duration, growth, and developmental milestones.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

950 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NYPOZI™ (FILGRASTIM-TXID)

HCPCS: Q5148

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

1560 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

NYVEPRIA™ (PEGFILGRASTIM-APGF)

HCPCS: Q5122

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

OCREVUS® (OCRELIZUMAB) AND OCREVUS ZUNOVO® (OCRELIZUMAB AND HYALURONIDASE-OCSQ)

HCPCS: J2350, J2351

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has been screened for Hepatitis B virus (HBV) prior to initiating treatment **AND** does not have active disease (i.e., positive HBsAg and anti-HBV tests); **AND**
- Member has a baseline assessment of serum immunoglobulin; **AND**
- Member will not receive live or live attenuated vaccines while on therapy or within 4 weeks prior to the initiation of treatment; **AND**
- Member is immunocompetent and free of an active infection; **AND**
- Member will have serum aminotransferases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]), alkaline phosphatase, and bilirubin levels measured at baseline and periodically throughout therapy; **AND**
- Ocrevus/Ocrevus Zunovo will be used as single therapy; **AND**
- Member has not received a dose of ocrelizumab or ublituximab within the past 5 months; **AND**
- Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
  - Member is at least 18 years of age; **AND**
    - Member has a diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS*], active secondary progressive disease [SPMS**], or clinically isolated syndrome [CIS***]); **OR**
    - Member has a diagnosis of primary progressive MS (PPMS)*; **AND**
      - Member is less than 65 years of age; **AND**
      - Member has an expanded disability status scale (EDSS) score of ≤ 6.5; **OR**
  - Member is at least 10 years of age (Ocrevus® only); **AND**
    - Member weighs 25 kg or more; **AND**
    - Member has a diagnosis of relapsing-remitting MS (RRMS*); **AND**
- Member has a documented trial and failure of **two** of the preferred Multiple Sclerosis agents (see Multiple Sclerosis on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- Ocrevus (IV): 300 billable units on day 1 and 15 then 600 billable units every 6 months
- Ocrevus Zunovo (SQ): 920 billable units every 6 months

Definitions

***Definitive diagnosis of relapsing-remitting MS (RRMS) or primary progressive MS (PPMS) is based upon:**

- Dissemination in space (see below) AND one or more of the following:
  - Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  - Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  - Dissemination in time (DIT) (see below)
  - Presence of lesions in at least four of five CNS anatomical locations; **OR**
- Lesions present in one CNS site (including members with 12 months or longer progression from onset) AND one or more of the following:
  - CSF positivity and CVS positivity
  - CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  - DIT (see below) and CVS positivity
  - DIT (see below) and PRL positivity

Unless contraindicated, MRI should be obtained (even if criteria are met).

Dissemination in time (development/appearance of new CNS lesions over time)

- ≥ 2 clinical attacks; **OR**
- Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR**
- A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI

Dissemination in space (development of lesions in distinct anatomical locations within the CNS; multifocal)

- MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR**
- In members with progressive disease (members with 12 months or longer progression from onset), two spinal cord lesions

****Active Secondary Progressive MS (SPMS) is defined as the following:**

- Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND**
- Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤ 5.5 or increase by 0.5 in patients with EDSS ≥ 6); **AND**
- At least 1 relapse within the previous 2 years; **OR**
- Member has gadolinium-enhancing activity or new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

*****Definitive diagnosis of CIS is based upon all of the following:**

- A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
- Neurologic symptom duration of at least 24 hours, with or without recovery

- Absence of fever or infection
- Member is not known to have multiple sclerosis

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

OMISIRGE® (OMIDUBICEL-ONLV)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have a known allergy or hypersensitivity to any of the following:
  - Dimethyl Sulfoxide (DMSO)
  - Dextran 40
  - Gentamicin
  - Human serum albumin
  - Bovine products; **AND**
- Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GVHD, infections, etc.) according to institutional guidelines; **AND**
- Member meets indication specific criteria below:

Umbilical cord blood transplantation (UCBT) following myeloablative conditioning in members with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection

- Member is at least 12 years of age; **AND**
- Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has not received a prior allo-HSCT; **AND**
- Member has a diagnosis of a high-risk hematologic malignancy and is planned for an umbilical cord blood transplantation (UCBT) following myeloablative conditioning; **AND**
- Therapy is used to reduce the time to neutrophil recovery and incidence of infection; **AND**
- Member has no readily available matched related donor (MRD), matched unrelated donor (MUD), mismatched (7/8 matched) unrelated donor (MMUD), or haploidentical (half HLA-matched) related donor.

Severe aplastic anemia (SAA) following reduced intensity conditioning

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of severe aplastic anemia (SAA) with severe neutropenia (i.e., ANC<1000 cells/µL) following reduced intensity conditioning; **AND**
- Member has tried and failed on or has an intolerance to standard immunosuppressive therapy; **AND**
- Member has an ECOG score of ≤1; **AND**
- Member has no readily available HLA identical (12/12) matched related or unrelated donor.

QUANTITY LIMITS

One dose only (single-use culture containing at least 12 x 10^8 live cells, which include CD34+ and CD3+ cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

OMVOH™ (MIRIKIZUMAB-MRKZ)

HCPCS: J2267

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Crohn's Disease

- 900 billable units at weeks 0, 4, and 8; then 300 billable units at week 12 and every 4 weeks thereafter

Ulcerative Colitis

- 300 billable units at weeks 0, 4, and 8; then 200 billable units at week 12 and every 4 weeks thereafter

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ONCASPAR® (PEGASPARGASE)

HCPCS: J9266

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 month of age; **AND**
- Member must not have a history of serious thrombosis or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Member must not have a history of pancreatitis, including pancreatitis related to prior L-asparaginase therapy; **AND**
- Member must not have severe hepatic impairment; **AND**
- Used as a component of a multi-agent chemotherapy; **AND**
- Member will receive premedication prior to administration of Oncaspar to decrease the risk and severity of both infusion and hypersensitivity reactions (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]); **AND**
- Member has a diagnosis of Acute Lymphoblastic Leukemia (ALL); **AND**
  - Member has a hypersensitivity to native forms of L-asparaginase; **OR**
  - Used as first line/induction therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 VIAL)

2 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ONPATTRO® (PATISIRAN LIPID COMPLEX)

HCPCS: J0222

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing or stabilizing agents (e.g., inotersen, tafamidis, vutrisiran, eplontersen, etc.); **AND**
- Member has a definitive diagnosis of Hereditary Transthyretin-Mediated (hATTR) Amyloidosis as identified by molecular genetic testing; **AND**
- Used for the treatment of polyneuropathy as demonstrated by at least TWO of the following criteria:
  - Subjective member symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; **AND**
- Member's peripheral neuropathy is attributed to hATTR and other causes of neuropathy have been excluded; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.); **AND**
- Member has not been the recipient of an orthotopic liver transplant (OLT).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

300 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

OPDIVO® (NIVOLUMAB)

HCPCS: J9299

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Therapy will not be used concomitantly with subcutaneous nivolumab.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

6960 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

OPDIVO QVANTIG™ (NIVOLUMAB AND HYALURONIDASE-NVHY)

HCPCS: J9289

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy unless otherwise specified Δ (Note: Not applicable when used as switch-therapy from intravenous nivolumab); **AND**
- Therapy will not be used concomitantly with intravenous nivolumab; **AND**
- Member meets indication specific criteria below:

Urothelial Carcinoma (Bladder Cancer)

- Member is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Used for locally advanced or metastatic disease that progressed during or following platinum-containing chemotherapy* OR progression with 12 months of neoadjuvant or adjuvant treatment with a platinum-containing regimen; **OR**
  - Used as adjuvant therapy in members who are at a high risk for disease recurrence** after undergoing surgical resection; **OR**
- Used in combination with cisplatin and gemcitabine; **AND**
  - Used as first line therapy in members with unresectable or metastatic disease.

Colorectal Cancer (CRC)

- Member is at least 12 years of age and weighs 30 kg or greater; **AND**
- Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
  - Used for unresectable or metastatic disease following combination treatment with intravenous nivolumab/ipilimumab; **OR**
  - Used as subsequent therapy for metastatic disease that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan regimen.

Gastric Cancer/Esophageal Cancer/Gastroesophageal Junction (GEJ) Cancer

- Member is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Used as adjuvant treatment of completely resected esophageal or GEJ cancer with residual pathologic disease in members who have received neoadjuvant chemoradiotherapy (CRT).; **OR**
  - Used as subsequent therapy after prior fluoropyrimidine- and platinum-based chemotherapy; **AND**
    - Used for unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC); **OR**

- Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
  - Used as first-line therapy; AND
  - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test; **AND**
    - Used in members with unresectable, advanced or metastatic esophageal squamous cell carcinoma (ESCC); **OR**
    - Used for advanced or metastatic gastric, GEJ, or esophageal adenocarcinomas.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- Member is at least 18 years of age; **AND**
- Used as single-agent therapy; **AND**
- Member has metastatic disease with disease progression on or after platinum-based therapy; **AND**
- Member does not have disease of the nasopharynx.

Hepatocellular Carcinoma (HCC)

- Member is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Member has unresectable or metastatic disease; **AND**
  - Used as first-line therapy following combination treatment with intravenous nivolumab/ipilimumab; **OR**
  - Used as subsequent therapy after being previously treated with sorafenib and following combination treatment with intravenous nivolumab/ipilimumab.

Renal Cell Carcinoma (RCC)

- Member is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Used as first line therapy in members with intermediate or poor risk advanced disease following treatment with intravenous nivolumab/ipilimumab; **OR**
  - Used as subsequent therapy after prior anti-angiogenic therapy; **OR**
- Used in combination with cabozantinib (Cabometyx only); **AND**
  - Used as first-line therapy for advanced disease.

Cutaneous Melanoma

- Member is at least 12 years of age and weighs 30 kg or greater; **AND**
- Used as single agent therapy; **AND**
  - Used as first-line therapy for unresectable or metastatic disease; **OR**
  - Used as subsequent therapy for unresectable or metastatic disease following treatment with intravenous nivolumab/ipilimumab; **OR**
  - Used as adjuvant treatment and member has stage IIB, stage IIC, stage III or metastatic disease and has undergone complete resection.

Non-Small Cell Lung Cancer (NSCLC)

- Member is at least 18 years of age; **AND**

- Used as single-agent therapy; **AND**
  - Used for metastatic disease; **AND**
  - Used as subsequent therapy on or after platinum-based chemotherapy (Note: Members with EGFR or ALK genomic tumor aberrations should have disease progression on targeted therapies prior to receiving subcutaneous nivolumab); **OR**
- Used in combination with platinum-doublet chemotherapy; **AND**
  - Used as neoadjuvant therapy in members who have resectable (tumors greater than or equal to 4 cm or node positive) disease; **OR**
  - Used as neoadjuvant therapy in resectable disease with the option of continuing to single-agent subcutaneous nivolumab therapy as adjuvant treatment after surgery.

∆ Notes:

- Members responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Members previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Members who complete adjuvant therapy and progress at least 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.
- Members diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with nivolumab as subsequent therapy and will be evaluated on a case-by-case basis

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

600 billable units every 4 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

OPDUALAG™ (NIVOLUMAB/RELATLIMAB-RMBW)

HCPCS: J9298

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 12 years of age; **AND**
- Member weighs at least 40 kg; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy; **AND**
- Member has a diagnosis of unresectable or metastatic melanoma.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 3 MG NIVOLUMAB/1 MG RELATLIMAB-RMBW)

160 billable units (480 mg nivolumab/160 mg relatlimab) every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ORENCIA® (ABATACEPT)

HCPCS: J0129

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Prophylaxis of acute graft versus host disease

- 400 billable units every 29 days

All other indications

- 100 billable units at weeks 0, 2, and 4 then 100 billable units every 4 weeks

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

OXLUMO® (LUMASIRAN)

HCPCS: J0224

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not had a liver transplant; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics, nephrology, or urology; **AND**
- Will not be used in combination with other urinary oxalate reducing agents; **AND**
- Member has a definitive diagnosis of primary hyperoxaluria type 1 (PH1) as evidenced by one of the following:
  - Member has a biallelic pathogenic mutation in the alanine: glyoxylate aminotransferase (AGXT) gene as identified on molecular genetic testing; **OR**
  - Identification of alanine: glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; **AND**
- Member has a baseline for one or more of the following:
  - Urinary oxalate excretion level (corrected for BSA)
  - Spot urinary oxalate: creatinine ratio
  - Estimated glomerular filtration rate (eGFR)
  - Plasma oxalate level.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

756 billable units every 28 days for 3 doses then every 84 days thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

OZURDEX® (DEXAMETHASONE IMPLANT)

HCPCS: J7312

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections (including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases, etc.); **AND**
- Member does not have glaucoma with a cup to disk ratio of greater than 0.8; **AND**
- Member does not have a torn or ruptured posterior lens capsule; **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically throughout treatment; **AND**
- Member's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Member has one of the following diagnoses:
  - Diabetic Macular Edema (DME); **OR**
  - Macular Edema Following Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO); **OR**
  - Non-Infectious Uveitis Affecting the Posterior Segment of the Eye.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

14 billable units every 4 months

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PADCEV® (ENFORTUMAB VEDOTIN-EJFV)

HCPCS: J9177

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used in combination with pembrolizumab; **AND**
  - Member has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma; **OR**
    - Muscle invasive bladder cancer (MIBC); **AND**
      - Used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment for cisplatin ineligible for members; **OR**
- Used as a single agent; **AND**
  - Member has locally advanced or metastatic urothelial carcinoma; **AND**
  - Used in one of the following treatment settings:
    - Member was previously treated with platinum-containing chemotherapy and a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor; **OR**
    - Used in members ineligible for cisplatin-containing chemotherapy after one or more prior lines of therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.25 MG)

4680 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PALONOSETRON

HCPCS: J2468, J2469

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered prior to surgery or alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 25 MCG)

10 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

PAPZIMEOS™ (ZOPAPOGENE IMADENOVEC-DRBA)

HCPCS: J3404

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a confirmed histological diagnosis of recurrent respiratory papillomatosis; **AND**
- Surgical debulking of any present visible papilloma will be performed prior to the initial, third and fourth injections; **AND**
- Member has the presence of laryngotracheal papillomas; **AND**
- Member has required 3 or more interventions (e.g., surgery, systemic therapy, etc.) in the last 12 months for control of respiratory papillomatosis.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

One dose (5×10^{11} particle units per dose) on day 1, day 12, week 6, and week 12

LENGTH OF AUTHORIZATION

6 months (four doses total) for initial approval, not eligible for renewal

PEDMARK® (SODIUM THIOSULFATE)

HCPCS: J0208

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have a serum sodium level greater than 145 mmol/L (145 mEq/L); **AND**
- Member is at least 1 month of age and less than 18 years of age; **AND**
- Member has a localized, non-metastatic solid tumor; **AND**
- Member is receiving cisplatin infusions that are 1 to 6 hours in duration and the next cisplatin infusion is scheduled to be in more than 10 hours.

Note: Any other use of Pedmark will be allowed ONLY when:

- Sodium thiosulfate (12.5 g/50 mL) is not obtainable as confirmed by the FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 100 MG)

500 billable units every 14 days

LENGTH OF AUTHORIZATION

12 weeks for initial approval, 12 weeks for renewal

PEMETREXED

HCPCS: J9292, J9294, J9296, J9297, J9304, J9305, J9314, J9322, J9323, J9324

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets the indication specific criteria below:

Pleural Mesothelioma

- Used as induction therapy prior to surgical exploration; **AND**
  - Member has clinical stage I disease and epithelioid histology; **AND**
    - Used as a single agent OR in combination with platinum chemotherapy with or without either bevacizumab or pembrolizumab; **OR**
- Used as first-line therapy; **AND**
  - Used as a single agent OR in combination with platinum chemotherapy with or without either bevacizumab or pembrolizumab; **OR**
- Used as subsequent therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with platinum chemotherapy with or without bevacizumab; **AND**
    - Immunotherapy (i.e., nivolumab/ipilimumab) was administered as first-line treatment; **OR**
    - Used as a rechallenge if pemetrexed-based treatment was administered first-line with good response.

Non-Squamous Non-Small Cell Lung Cancer (NS-NSCLC)

- Used in combination with a carboplatin or cisplatin-containing regimen; **OR**
- Used in combination with bevacizumab, pembrolizumab, cemiplimab, or durvalumab for continuation maintenance therapy if previously used first-line and member achieved a tumor response or stable disease following initial therapy; **OR**
- Used as a single agent; **AND**
  - Member has recurrent, advanced, or metastatic disease; **AND**
    - Used as first-line therapy for tumors that are negative for actionable biomarkers; **OR**
    - Used as first-line therapy for EGFR exon 20 insertion mutation, BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, NRG1 gene fusion, or ERBB2 (HER2) mutation positive tumors; **OR**
    - Used as subsequent therapy; **OR**
    - Used as continuation or switch maintenance therapy in members who have achieved a tumor response or stable disease following initial therapy.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

230 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PERJETA® (PERTUZUMAB)

HCPCS: J9306

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive breast cancer as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used as neoadjuvant therapy; **AND**
  - Member has locally advanced, inflammatory, or early stage disease (either greater than 2 cm in diameter or node positive); **AND**
  - Used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen for early breast cancer; **OR**
- Used as adjuvant therapy; **AND**
  - Member has early breast cancer at high risk of recurrence; **AND**
  - Used in combination with trastuzumab and chemotherapy; **OR**
- Used for metastatic disease in members who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
  - Used in combination with trastuzumab and docetaxel.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

840 billable units for loading dose then 420 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PHESGO® (PERTUZUMAB, TRASTUZUMAB AND HYALURONIDASE-ZZXF)

HCPCS: J9316

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive breast cancer as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be used in combination with pertuzumab or any trastuzumab-based formulation; **AND**
- Therapy will not be substituted for or with pertuzumab or any trastuzumab-based formulation; **AND**
- Used as neoadjuvant therapy; **AND**
  - Member has locally advanced, inflammatory, or early-stage disease; **AND**
  - Used in combination with chemotherapy; **OR**
- Used as adjuvant therapy; **AND**
  - Member has early disease at high risk of recurrence; **OR**
- Used for metastatic disease; **AND**
  - Member has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
    - Used combination with docetaxel.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

180 billable units for loading dose then 120 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PIASKY® (CROVALIMAB-AKKZ)

HCPCS: J1307

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (lab tests required); **AND**
- Member is at least 13 years of age; **AND**
- Member weighs at least 40 kg; **AND**
- Must be prescribed by, or in consultation with, a hematologist or other specialist in paroxysmal nocturnal hemoglobinuria; **AND**
- Member will not use requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), or Empaveli (pegcetacoplan); **AND**
- Member must not have unresolved serious *Neisseria meningitidis* infection.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Loading Dose

- 170 billable units IV on day 1; 34 billable units SQ on days 2, 8, 15, and 22; 102 billable units SQ on day 29

Maintenance Dose

- 102 billable units SQ every 4 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

POLIVY® (POLATUZUMAB VEDOTIN-PIIQ)

HCPCS: J9309

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member will receive prophylaxis for Pneumocystis jirovecii pneumonia and herpesvirus; **AND**
- Member does not currently have Grade ≥ 2 peripheral neuropathy; **AND**
- Member does not have CNS lymphoma; **AND**
- Used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP); **AND**
  - Member has a diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL), not otherwise specified (NOS) or High-Grade B-Cell Lymphoma (HGBL); **AND**
    - Used as first line therapy; **AND**
      - Member has an International Prognostic Index (IPI) score of ≥2; **OR**
- Used in combination with bendamustine and a rituximab product; **AND**
  - Member has a diagnosis of DLBCL, NOS; **AND**
    - Member has received at least two (2) prior lines of therapy.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

200 billable units every 21 days, for up to 6 cycles

LENGTH OF AUTHORIZATION

6 months for initial approval, not eligible for renewal

POMBILITI® (CIPAGLUCOSIDASE ALFA-ATGA)

HCPCS: J1203

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has documented baseline values for percent predicted forced vital capacity (FVC) and/or 6-minute walk test (6MWT); **AND**
- Females of reproductive potential must have a negative pregnancy test prior to initiating therapy and will use effective methods of contraception during treatment; **AND**
- Member is experiencing an inadequate response or intolerance to their current enzyme replacement therapy; **AND**
- Will not be used in combination with other enzyme replacement therapies; **AND**
- Will be used in combination with the enzyme stabilizer formulation miglustat (Opfolda); **AND**
- Members susceptible to fluid volume overload or those with an acute underlying respiratory illness or compromised cardiac or respiratory function, will be closely monitored for exacerbation of their cardiac or respiratory status during infusion; **AND**
- Member has an actual body weight of at least 40 kilograms; **AND**
- Member has a diagnosis of Pompe Disease (Acid Alpha-Glucosidase (GAA) deficiency) as confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase (GAA) enzyme activity; **OR**
  - Detection of biallelic pathogenic variants in the GAA gene by molecular genetic testing; **AND**
- Member has a diagnosis of late-onset (non-infantile) disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member is being monitored for antibody formation (including neutralizing antibodies).

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

462 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

POTELIGEO® (MOGAMULIZUMAB-KPKC)

HCPCS: J9204

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as single agent systemic therapy; **AND**
- Member has a diagnosis of relapsed or refractory mycosis fungoides or Sézary syndrome; **AND**
- Member has tried and failed at least one other systemic therapy; **AND**
- Member has not had prior allogeneic hematopoietic stem cell transplant (HSCT) or autologous HSCT within the last 90 days; **AND**
- Member is free of active autoimmune disease or active infections; **AND**
- Member has no evidence of CNS metastases; **AND**
- If female, member must not be pregnant; verification of pregnancy status should be performed prior to starting therapy; **AND**
- If female, member must be using contraception during therapy and for 3 months after cessation of therapy.

RENEWAL CRITERIA

- Member continues to meet the initial approval criteria above; **AND**
- Member has not experienced disease progression or stabilization of disease; **AND**
- Member has not experienced unacceptable toxicities (e.g., history of Stevens-Johnson syndrome, toxic epidermal necrolysis, life-threatening infusion reaction, and autoimmune complications).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

120 billable units on days 1, 8, 15, and 22 of the first 28-day cycle, then 120 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

PROVENGE® (SIPULEUCEL-T)

HCPCS: Q2043

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has castration-resistant metastatic prostate cancer; **AND**
- Member has an ECOG Performance status of 0-1; **AND**
- Member does not have liver metastases; **AND**
- Must not be used in combination with chemotherapy; **AND**
- Member is asymptomatic or minimally symptomatic; **AND**
- Member has not previously received therapy with sipuleucel-T.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit every 14 days for 3 doses only

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

QALSODY® (TOFERSEN)

HCPCS: J1304

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a baseline measure of the plasma neurofilament light chain (NfL); **AND**
- Member has a diagnosis of clinically definite or probable Amyotrophic Lateral Sclerosis (ALS) based on El Escorial revised criteria, Gold Coast criteria, or Awaji criteria; **AND**
- Member has the presence of a mutation in the superoxide dismutase 1 (SOD1) gene: **AND**
- Member has a slow vital capacity (%SVC) ≥ 65%.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

100 billable units every 14 days for first 3 doses, then 100 billable units every 28 days thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

QUTENZA® (CAPSAICIN)

HCPCS: J7336

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Neuropathic Pain agents on the PDL (see Neuropathic Pain and Select Agents on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 CM^2)

1120 billable units every 90 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

RADICAVA® (EDARAVONE)

HCPCS: J1301

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Will not be used in combination with other formulations of edaravone (i.e., oral); **AND**
- Member has a diagnosis of clinically definite or probable Amyotrophic Lateral Sclerosis (ALS) based on El Escorial revised criteria, Gold Coast criteria, or Awaji criteria; **AND**
- Member has a disease duration of 2 years or less; **AND**
- Member has a percent-predicted forced vital capacity (%FVC) ≥ 80%; **AND**
- Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)].

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

60 billable units daily on days 1-14 of the first 28 day cycle, then 600 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

RANIBIZUMAB FOR INTRAVITREAL USE VIA SUSVIMO® OCULAR IMPLANT

HCPCS: J2779*

*This code applies to the product Susvimo® only

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors, unless supplemental treatment with another ranibizumab product is necessary; **AND**
- Member has not required removal of a Susvimo implant in the past; **AND**
- Member does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis, Byooviz, Cimerli, etc.); **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member has previously responded to at least two intravitreal injections of a VEGF inhibitor medication; **AND**
- Member has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - Diabetic Macular Edema (DME)
  - Diabetic Retinopathy (DR)

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

200 billable units every 24 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

RANIBIZUMAB FOR INTRAVITREAL INJECTION

HCPCS: J2778, Q5124, Q5128*

*These codes apply to the following products: Byooviz™, Cimerli™, Lucentis®

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors^; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - Diabetic Macular Edema (DME) *(Lucentis® and Cimerli™ only)*
  - Diabetic Retinopathy (DR) *(Lucentis® and Cimerli™ only)*
  - Macular Edema following Retinal Vein Occlusion (RVO)
  - Myopic Choroidal Neovascularization (mCNV).

^Note: : Ranibizumab may be used as 'supplemental-treatment' in conjunction with Susvimo (ranibizumab via ocular implant) for Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), or Diabetic Retinopathy (DR), if clinically necessary

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

10 billable units every 28 days

LENGTH OF AUTHORIZATION

Myopic Choroidal Neovascularization (mCNV):

- 3 months for initial approval, 3 months for renewal

All other indications:

- 12 months for initial approval, 12 months for renewal

RELEUKO® (FILGRASTIM-AYOW)

HCPCS: Q5125

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

1560 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

REMODULIN® (TREPROSTINIL)

HCPCS: J3285

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- One of the following:
  - Member requires transition from epoprostenol to reduce the rate of clinical deterioration; **OR**
  - Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND ALL of the following:
    - Member's diagnosis was confirmed by right heart catheterization; **AND**
    - Member has a mean pulmonary arterial pressure greater than 20 mmHg; **AND**
    - Member has a pulmonary capillary wedge pressure less than or equal to 15 mmHg; **AND**
    - Member has a pulmonary vascular resistance greater than or equal to 3 Wood units; **AND**
    - Member's World Health Organization (WHO) functional Class is II or greater; **AND**
    - ONE of the following:
      - The requested agent will be utilized as monotherapy; **OR**
      - The requested agent will be utilized for add-on therapy to existing monotherapy AND BOTH of the following:
        - Member has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
        - All agents in the regimen are from a different therapeutic class (e.g., PDE-5 inhibitors, endothelin receptor antagonist, soluble guanylate cyclase stimulator); **OR**
      - The requested agent will be utilized for add-on therapy to existing dual therapy AND ALL of the following:
        - Member is WHO functional class III or IV; **AND**
        - Member has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
        - All agents in the regimen are from a different therapeutic class (e.g., PDE-5 inhibitors, endothelin receptor antagonist, soluble guanylate cyclase stimulator); **OR**
      - The requested agent will be utilized as part of triple therapy in a treatment naive member AND both of the following:
        - Member is WHO functional class IV; **AND**
        - The 3 agents being utilized consist of: endothelin receptor antagonist (ERA) plus PDE5 inhibitor plus prostanoid; **AND**
- If the request is for a brand agent (Remodulin®) member must have an intolerance, hypersensitivity, or contraindication to the generic equivalent that is not expected to occur with the brand agent; **OR**
  - There is support for the use of the requested brand agent over the generic equivalent; **AND**
- Prescribed by, or in consultation with, a specialist (e.g., cardiologist, pulmonologist); **AND**

- Member will NOT be using the requested agent in combination with another prostanoid agent for the requested indication.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

7 billable units every day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

RETHYMIC® (ALLOGENEIC PROCESSED THYMUS TISSUE-AGDC)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Used for immune reconstitution in pediatric members; **AND**
- Member has a diagnosis of congenital athymia based on flow cytometry documenting fewer than 50 naïve T cells/mm^3 (CD45RA+, CD62L+) in the peripheral blood or less than 5% of total T cells being naïve in phenotype (Note: Requests for naïve T-cell counts ≥50 cells/mm^3 will be handled on a case-by-case basis); **AND**
  - Member has athymia with a diagnosis of FOXN1 deficiency; **OR**
  - Member has complete DiGeorge syndrome (cDGS), also referred to as complete DiGeorge anomaly (cDGA); **AND**
- Will not be used for the treatment of members with severe combined immunodeficiency (SCID); **AND**
- Will not be used in members with any of the following:
  - Heart surgery anticipated within 4 weeks prior to, or 3 months after, the planned Rethymic treatment date
  - Human immunodeficiency virus (HIV) infection
  - Deemed to be poor surgical candidates; **AND**
- Benefits and risks of treatment have been discussed with members who have a pre-existing cytomegalovirus (CMV) infection or who have renal impairment; **AND**
- Member has been screened for anti-HLA antibodies; **AND**
- Member will receive IVIG replacement and prophylactic antimicrobials prior to and after transplant until immune reconstitution (according to infection control protocols) occurs; **AND**
- Member will not receive live or inactivated vaccines until IVIG/immunosuppressive therapy is discontinued and immune reconstitution has occurred; **AND**
- Members with elevated baseline T cell proliferative response to phytohemagglutinin (PHA) greater than or equal to 5,000 cpm or greater than 20-fold over background or have evidence of maternal engraftment will receive combination therapy with immunosuppressive agents (e.g., rabbit antithymocyte globulin with or without calcineurin inhibitors and/or steroids).

QUANTITY LIMITS

Up to 42 slices (approximately 55,000 mm^2) of Rethymic

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

RETISERT® (FLUOCINOLONE ACETONIDE IMPLANT)

HCPCS: J7311

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is free of ocular and/or periocular infections (including active epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella, mycobacterial infections, and fungal diseases, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Member has a diagnosis of Chronic Noninfectious Uveitis Affecting the Posterior Segment of the Eye; **AND**
- Member is at least 12 years of age; **AND**
- Member has had chronic disease for at least one year; **AND**
- Other causes of uveitis have been ruled out (e.g., infection, malignancy, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.01 MG)

118 billable units every 30 months

LENGTH OF AUTHORIZATION

1 implant per eye every 30 months for initial approval, 1 implant per eye every 30 months for renewal

REVCOVI® (ELAPEGADEMASE-LVLR)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have severe thrombocytopenia (i.e., platelet count <50,000/µL); **AND**
- Member has adenosine deaminase severe combined immunodeficiency (ADA-SCID) disease as determined by one of the following:
  - Deficient ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); **OR**
  - Detection of biallelic pathogenic mutations in the ADA gene by molecular genetic testing; **AND**
- Member has elevated deoxyadenosine triphosphate (dATP) or total deoxyadenosine nucleotides (dAXP) in red blood cells; **AND**
  - Member is not a candidate for or has failed definitive therapy with bone marrow transplantation (BMT); **OR**
  - Member is a candidate for definitive therapy with BMT and elapegademase will be used as bridge therapy; **AND**
- Member has baseline values for trough plasma ADA activity, red blood cell dATP, trough red blood cell dAXP, and/or total lymphocyte counts.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS

23 mg twice weekly

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

RITUXIMAB

HCPCS: J9312, Q5115, Q5119, Q5123

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age, unless otherwise specified; **AND**
- Member does not have a severe, active infection; **AND**
- Member has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and members with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Provider will confirm that member has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Member is CD20 antigen expression positive (*for oncology indications only); **AND**
- Member meets indication specific criteria below:

Pediatric Mature B-Cell Acute Leukemia (B-AL)

- Member is at least 6 months of age; AND
- Used in combination with chemotherapy for previously untreated disease.

Chronic Lymphocytic Leukemia (CLL)

- Used in combination with fludarabine and cyclophosphamide.

Adult Non-Hodgkin's Lymphoma (NHL)

- Member has relapsed or refractory, low grade or follicular, B-Cell NHL; **AND**
  - Used as a single agent; **OR**
- Member has previously untreated follicular B-cell NHL; **AND**
  - Used in combination with first line chemotherapy; **OR**
  - Used as a single-agent maintenance therapy in members achieving a complete or partial response to a rituximab product in combination with chemotherapy; **OR**
- Member has non-progressing (including stable disease), low-grade B-cell NHL; **AND**
  - Used as a single agent; **AND**
  - Used after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy; **OR**
- Member has previously untreated diffuse large B-cell NHL; **AND**
  - Used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens.

Pediatric Aggressive Mature B-Cell Lymphomas

- Member is at least 6 months of age; **AND**
  - Used in combination with chemotherapy for one of the following:
    - Diffuse Large B-Cell Lymphoma
    - Burkitt Lymphoma

- Burkitt-like Lymphoma.

Rheumatoid Arthritis (RA)

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
- Used in combination with methotrexate unless the member has a contraindication or intolerance; **AND**
  - Member tried and failed at least a 3-month trial with ONE conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.); **OR**
  - Member is already established on biologic or targeted synthetic therapy for the treatment of RA; **AND**
- Previous failure with one or more TNF antagonists; **AND**
- Member has not had treatment with rituximab in the previous 4 months.

Pemphigus Vulgaris

- Member has a diagnosis of pemphigus vulgaris as determined by the following:
  - Member has one or more of the following clinical features:
    - Appearance of lesions, erosions and/or blisters
    - Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)
    - Characteristic scarring and lesion distribution; **AND**
  - Histopathologic confirmation by skin/mucous membrane biopsy; **AND**
  - Positive direct immunofluorescence (DIF) microscopy result OR the presence of autoantibodies as detected by indirect immunofluorescence (IIF) or enzyme-linked immunosorbent assay (ELISA); **AND**
- Member has moderate to severe disease as assessed utilizing an objective measure/tool (e.g., PDAI, PSS, ABSIS, etc.); **AND**
- Used in combination with a tapering course of glucocorticoids (e.g., prednisone, prednisolone, etc.); **AND**
- Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Member is at least 2 years of age; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Pediatric Mature B-Cell Acute Leukemia (B-AL)

- 100 billable units twice weekly

Chronic Lymphocytic Leukemia (CLL)

- Initial therapy: 100 billable units for 1 dose, then 130 billable units every 7 days for 11 doses
- Renewal therapy: 130 billable units every 8 weeks

Adult Non-Hodgkin's Lymphoma (NHL)

- Initial therapy: 100 billable units every 7 days x 8 doses in a 6 month period
- Renewal therapy: 800 billable units every 168 days

Pediatric Aggressive Mature B-Cell Lymphomas

- 100 billable units twice weekly

Rheumatoid Arthritis (RA)

- 200 billable units every 24 weeks

Pemphigus Vulgaris

- Initiation: 100 billable units every 7 days for 4 doses in a 12 month period
- Maintenance: 50 billable units every 6 months

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- Induction: 100 billable units every 7 days for 4 doses
- Initial Maintenance: 100 billable units every 14 days for 2 doses
- Subsequent Maintenance: 100 billable units every 6 months

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RITUXAN HYCELA® (RITUXIMAB AND HYALURONIDSE HUMAN)

HCPCS: J9311

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Member does not have a severe, active infection; **AND**
- Member has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and members with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Member is CD20 antigen expression positive; **AND**
- Rituxan Hycela will not be used with intravenous chemotherapy agents or intravenous radioimmunotherapy; **AND**
- Provider will confirm that member has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Member has a diagnosis of one of the following:
  - Chronic Lymphocytic Leukemia
  - Follicular Lymphoma (FL)
  - Diffuse Large B-Cell Lymphoma (DLBCL).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

560 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RIVFLOZA® (NEDOSIRAN)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age; **AND**
- Member has not had a kidney or liver transplant; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics, nephrology, or urology; **AND**
- Member does not have severe renal impairment defined as an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m2; **AND**
- Will not be used in combination with other urinary oxalate reducing agents; **AND**
- Member has a definitive diagnosis of primary hyperoxaluria type 1 (PH1) as evidenced by one of the following:
  - Member has a biallelic pathogenic mutation in the alanine: glyoxylate aminotransferase (AGXT) gene as identified on molecular genetic testing; **OR**
  - Identification of alanine: glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; **AND**
- Member has a baseline for one or more of the following:
  - Urinary oxalate excretion level (corrected for BSA)
  - Spot urinary oxalate: creatinine ratio
  - Estimated glomerular filtration rate (eGFR)
  - Plasma oxalate level.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member continues to experience clinical benefit from the requested treatment.

QUANTITY LIMITS

160 mg every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ROLVEDON® (EFLAPEGRASTIM-XNST)

HCPCS: J1449

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

Acute Radiation Exposure

- 132 billable units weekly for 2 doses

All other indications

- 132 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

RUCONEST® (C1 ESTERASE INHIBITOR, RECOMBINANT)

HCPCS: J0596

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used as monotherapy for treatment of acute hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Member has tried and failed two preferred hereditary angioedema agents (see Hereditary Angioedema agents on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 UNITS)

3360 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

RYBREVANT® (AMIVANTAMAB-VMJW)

HCPCS: J9061

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been instructed/counseled on limiting sun exposure and the use of protective clothing and/or broad-spectrum UVA/UVB sunscreen; **AND**
- Therapy will not be used concomitantly with subcutaneous amivantamab; **AND**
- Member has locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
  - Used in combination with lazertinib; **AND**
    - Used as first-line treatment; **AND**
    - Member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test; **OR**
  - Used in combination with carboplatin and pemetrexed in members with nonsquamous histology; **AND**
    - Used as first-line therapy; **AND**
      - Member has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test; **OR**
    - Used as subsequent therapy; **AND**
      - Member has EGFR exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
      - Used following disease progression on or after treatment with an EFGR tyrosine kinase inhibitor (i.e., osimertinib); **OR**
  - Used as a single agent; **AND**
    - Used as subsequent therapy; **AND**
    - Member has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
    - Used following disease progression on or after treatment with platinum-based chemotherapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

875 billable units every 7 days for 5 weeks, no dose on week 6, then 2100 billable units every 42 days thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RYBREVANT FASPRO™ (AMIVANTAMAB AND HYALURONIDASE-LPUJ)

HCPCS: J9062

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been instructed/counseled on limiting sun exposure and the use of protective clothing and/or broad-spectrum UVA/UVB sunscreen; **AND**
- Therapy will not be used concomitantly with intravenous amivantamab; **AND**
- Member has locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
  - Used in combination with lazertinib; **AND**
    - Used as first-line treatment; **AND**
    - Member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test; **OR**
  - Used in combination with carboplatin and pemetrexed in members with nonsquamous histology; **AND**
    - Used as first-line therapy; **AND**
      - Member has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test; **OR**
    - Used as subsequent therapy; **AND**
      - Member has EGFR exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
      - Used following disease progression on or after treatment with an EFGR tyrosine kinase inhibitor (i.e., osimertinib); **OR**
  - Used as a single agent; **AND**
    - Used as subsequent therapy; **AND**
    - Member has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
    - Used following disease progression on or after treatment with platinum-based chemotherapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

448 billable units for 1 dose, then 672 billable units every 7 days for 3 doses, then 2,784 billable units every 84 days thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RYKINDO® (RISPERIDONE MICROSPHERES)

HCPCS: J2801

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred long-acting injectable atypical antipsychotic agents (see Atypical, Long-Acting Injectable Antipsychotics on the PDL).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

100 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

RYLAZE® (ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)-RYWN)

HCPCS: J9021

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 month of age; **AND**
- Member must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Member must not have severe hepatic impairment; **AND**
- Used as a component of multi-agent chemotherapy regimen; **AND**
- Member will receive premedication prior to administration of Rylaze to decrease the risk and severity of hypersensitivity reactions (e.g., acetaminophen, an H-1 receptor blocker [such as diphenhydramine], and an H-2 receptor blocker [such as famotidine]); **AND**
- Member has a diagnosis of Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL); **AND**
- Used as a substitute for E. coli-derived asparaginase (e.g., pegaspargase, calaspargase) in cases of hypersensitivity (e.g., systemic allergic reactions or anaphylaxis).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

2500 billable units every week

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RYONCIL® (REMESTEMCEL-L-RKND)

HCPCS: J3402

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 months of age; **AND**
- Member has steroid-refractory acute Graft-Versus-Host Disease (aGVHD) (defined as disease that shows progression within 3 days, or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent); **AND**
- Member does not have skin-only involvement or evidence of encephalopathy or diffuse alveolar hemorrhage or other active pulmonary disease; **AND**
- Member does not have a known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins; **AND**
- Member is post-allogeneic stem cell transplant (Note: Symptoms of aGVHD typically appear before day 100); **AND**
- For members 12 years of age and older, member has had an inadequate response to an adequate trial of, or contraindication or intolerance to ruxolitinib.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
  - Member has experienced at minimum a partial response (defined as organ improvement of at least 1 stage without worsening in any other organ) OR a mixed response (defined as improvement in at least 1 evaluable organ with worsening in another); **AND**
    - Member will require treatment with four additional (weekly) doses; **OR**
  - Member is experiencing an aGVHD flare after achieving a complete response [CR]); **AND**
    - Member will require treatment with eight additional (twice weekly) doses.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

225 million mesenchymal stromal cells (one therapeutic dose) twice a week for 4 weeks (up to 16 total doses)

LENGTH OF AUTHORIZATION

1 month for initial approval, 1 month for renewal

RYSTIGGO® (ROZANOLIXIZUMAB-NOLI)

HCPCS: J9333

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of generalized Myasthenia Gravis (gMG) **and all** of the following:
  - **One** of the following:
    - Member has a positive serological test for anti-AChR antibodies; **OR**
    - Member has a positive serological test for anti-MuSK antibodies; **AND**
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - **Both** of the following:
    - Member has a MG-Activities of Daily Living total score of greater than or equal to 3; **AND**
    - At least 3 points are from non-ocular symptoms; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
- Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis; **AND**
- Member will **not** be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

840 billable units weekly for 6 doses per 63 days (5040 billable units per 63 days)

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

RYTELO® (IMETELSTAT)

HCPCS: J0870

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has lower risk disease (defined as IPSS low- to intermediate-1) myelodysplastic syndrome; **AND**
  - Member is relapsed or refractory to ESA therapy or is ESA ineligible (i.e., EPO > 500 mU/mL); **AND**
  - Member is red blood cell (RBC) transfusion dependent, defined as requiring at least 4 RBC units transfused over an 8-week period.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

940 billable units every 4 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

RYZNEUTA® (EFBEMALENOGRASTIM ALFA-VUXW)

HCPCS: J9361

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 40 billable units weekly for 2 doses

All other indications

- 40 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SANDOSTATIN® (OCTREOTIDE ACETATE)

HCPCS: J2354

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has one of the following indications:
  - Vasoactive Intestinal Peptide Tumors (VIPomas)
  - Acromegaly
  - Carcinoid Tumors.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 25 MCG)

30 billable units every day

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

SANDOSTATIN® LAR (OCTREOTIDE SUSPENSION)

HCPCS: J2353

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets indication specific criteria below:

Carcinoid Tumors

- Member has severe diarrhea/flushing episodes associated with metastatic carcinoid tumors.

Diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas)

- Member has profuse watery diarrhea.

Acromegaly

- Member's diagnosis is confirmed by one of the following:
  - Unequivocally elevated (age-adjusted) serum insulin-like growth factor-1 (IGF-1); **OR**
  - Equivocally elevated (age-adjusted) serum IGF-1 AND inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Member has documented inadequate response to surgery and/or radiotherapy or it is not an option for the member; **AND**
- Used as long-term maintenance therapy; **AND**
- Baseline GH and IGF-1 blood levels have been obtained (renewal will require reporting of current levels).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

40 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

SAPHNELO® (ANIFROLUMAB-FNIA)

HCPCS: J0491

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of active moderate to severe systemic lupus erythematosus (SLE); **AND**
- Member does not have severe active lupus nephritis or severe active central nervous system lupus; **AND**
- Member is currently treated with and will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide); **AND**
- Must be prescribed by, or in consultation with, a rheumatologist or other specialist in systemic lupus erythematosus.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units (300 mg) every 4 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SARCLISA® (ISATUXIMAB-IRFC)

HCPCS: J9227

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies; **AND**
- Member has a diagnosis of Multiple Myeloma; **AND**
- Used as primary therapy for symptomatic disease; **AND**
  - Used in combination with bortezomib, lenalidomide, and dexamethasone; **OR**
  - Used in combination with carfilzomib, lenalidomide, and dexamethasone followed by maintenance therapy in combination with carfilzomib and lenalidomide (transplant candidates ONLY); **OR**
- Used for relapsed, refractory, or progressive disease; **AND**
  - Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.); **OR**
  - Used in combination with carfilzomib and dexamethasone.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

120 billable units weekly for 5 doses, then 720 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

SCENESSE® (AFAMELANOTIDE)

HCPCS: J7352

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have any malignant or premalignant skin lesions (e.g., melanoma, dysplastic nevus syndrome, Bowen's disease, basal cell or squamous cell carcinomas, etc.) as evidenced by a baseline full body skin examination for pre-existing skin lesions; **AND**
- Member has a definitive diagnosis of erythropoietic protoporphyria as confirmed by one of the following:
  - Elevated free protoporphyrin in peripheral erythrocytes; **OR**
  - Identification of biallelic pathogenic variants in ferrochelatase (FECH) on molecular genetic testing; **AND**
- Used to increase the pain free light exposure in members with a history of phototoxic reactions; **AND**
- Member will continue to maintain sun and light protection measures during treatment to prevent phototoxic reactions.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Member is being monitored with full body skin examinations (twice yearly) for pre-existing or new skin pigmentary lesions.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

16 billable units every 2 months

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SIGNIFOR® LAR (PASIREOTIDE)

HCPCS: J2502

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Confirmation that fasting plasma glucose, hemoglobin A1c, liver enzyme tests, electrocardiogram (ECG), gallbladder ultrasound, serum magnesium and serum potassium have been evaluated prior to starting treatment; **AND**
- Members with diabetes mellitus have stable glycemic control and are on optimized anti-diabetic treatment prior to the start of therapy; **AND**
- Member does not have severe hepatic impairment (i.e., Child-Pugh Class C); **AND**
- Member has not received a long-acting somatostatin analog within the last 4 weeks; **AND**
- Member meets indication specific criteria below:

Acromegaly

- Member's diagnosis is confirmed by one of the following:
  - Unequivocally elevated (age-adjusted) serum insulin-like growth factor-1 (IGF-1); **OR**
  - Equivocally elevated (age-adjusted) serum IGF-1 AND inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Member has documented inadequate response to surgery and/or radiotherapy or it is not an option for the member; **AND**
- Baseline GH and IGF-1 blood levels have been obtained (renewal will require reporting of current levels); **AND**
- Will not be used in combination with oral octreotide or with GH-analog (e.g., pegvisomant).

Cushing's Disease

- Confirmed diagnosis of endogenous Cushing's disease in which the member's hypercortisolism is not a result of chronic administration of high-dose glucocorticoids or other physiologic conditions; **AND**
- Treatment of member's disease with pituitary surgery has not been curative OR the member is not a candidate for pituitary surgery; **AND**
- Baseline 24-hour urinary free cortisol (UFC) level, Adrenocorticotropic hormone (ACTH), late-night salivary cortisol (LNSC), and/or serum cortisol level have been obtained (renewal will require reporting of current levels).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

60 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SIMPONI ARIA® (GOLIMUMAB IV)

HCPCS: J1602

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

250 billable units on weeks 0 and 4 then 250 billable units every 8 weeks

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

SKYRIZI® (RISANKIZUMAB-RZAA)

HCPCS: J2327

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1200 billable units every 4 weeks

LENGTH OF AUTHORIZATION

11 weeks for initial approval, not eligible for renewal

SKYSONA™ (ELIVALDOGENE AUTOTEMCEL)

HCPCS: J3387

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is assigned male at birth, at least 4 years of age and less than 18 years of age; **AND**
- Member does not have an available human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant (HSCT); **AND**
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 and 2 (HIV-1/HIV-2), and human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines prior to collection of cells for manufacturing; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection according to best clinical practices and guidelines; **AND**
- Vaccinations will not be administered within the 6 weeks prior to the start of therapy and will not be administered concurrently while on therapy **and** member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture); **AND**
- Member will receive periodic life-long monitoring for hematological malignancies (e.g., myelodysplastic syndrome [MDS]); **AND**
- Member does not have a full ABCD1 gene deletion; **AND**
- Member will avoid concomitant therapy with anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed (**Note**: if a member requires anti-retroviral for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization); **AND**
- Member does not have disease secondary to head trauma; **AND**
- Therapy will not be used to prevent the development of or treat adrenal insufficiency due to adrenoleukodystrophy; **AND**
- Member is eligible§ to undergo hematopoietic stem cell transplant (HSCT) and has not had a prior allogeneic-HSCT; **AND**
- Members capable of fathering a child and their partners of childbearing potential should use an effective method of contraception (e.g., intra-uterine device or combination of hormonal and barrier contraception) from start of mobilization through at least 6 months after administration of Skysona; **AND**
- Member has a documented diagnosis of cerebral adrenoleukodystrophy (CALD) as defined by one or more of the following:
  - Elevated very long chain fatty acids (VLCFA) as confirmed by the following:
    - Plasma C26:0-lysophosphatidylcholine (C26:0-LPC) level; **OR**
    - Fasting plasma VLCFA levels: C26:0, ratio of C24:0 to C22:0, **and** ratio of C26:0 to C22:0; **OR**
  - Pathogenic variants in the ABCD1 gene as detected by genetic testing; **AND**

- Member has active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating both of the following:
  - Loes score between 0.5 and 9 (inclusive) on the 34-point scale; **AND**
  - Gadolinium enhancement on MRI of demyelinating lesions; **AND**
- Neurologic Function Score (NFS) ≤ 1 (asymptomatic or mildly symptomatic disease)

§ Eligibility criteria for allogeneic HCT are not absolute and vary by center. In general, members are considered eligible for allogeneic HCT if they meet certain criteria like functional capacity, organ function, social support, etc.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

A single dose of Skysona containing a minimum of 5.0 x 10^6 CD34+ cells/kg of body weight, in one or more infusion bags.

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

SOLIRIS® (ECULIZUMAB)

HCPCS: J1299

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is free of *Neisseria meningitidis* infection; **AND**
- Member will **not** be using the requested agent in combination with Ultomiris (ravulizumab-cwvz), Bkemv (eculizumab-aeeb), or Epysqli (eculizumab-aagh); **AND**
- Member meets the indication specific criteria below:

Generalized Myasthenia Gravis (gMG)

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of generalized Myasthenia Gravis (gMG) **and all** of the following:
  - Member has a positive serological test for anti-AChR antibodies (medical records required); **AND**
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - Member has a MG-Activities of Daily Living total score of greater than or equal to 6; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
  - Member will **not** be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
- Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) **and all** of the following:
  - The diagnosis was confirmed by flow cytometry with at least 2 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 glycosylphosphatidylinositol (GPI)-linked proteins (lab tests required); **AND**

- Member will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Fabhalta (iptacopan), or Piasky (crovalimab-akkz).

Hemolytic Uremic Syndrome (aHUS)

- Member is at least 2 months of age; **AND**
- Member has a diagnosis of atypical Hemolytic Uremic Syndrome (aHUS) **and all** of the following:
  - Member is negative for Shiga toxin-producing E. coli (STEC); **AND**
  - The diagnosis was confirmed by **one** of the following: (medical records required)
    - Genetic mutation (e.g., CFH, CD46, CFI, C3, CFB, THBD, CFHR1, CFHR3, CFHR5); **OR**
    - Antibodies to complement factors; **OR**
    - A differential diagnosis of complement-mediated HUS has been demonstrated (i.e., screening for Shiga toxin-producing E. coli [STEC] for STEC-HUS, pneumococcal culture of blood/sputum/cerebrospinal or pleural fluid for pneumococcal-associated HUS, ADAMTS13 less than 10% activity for thrombotic thrombocytopenic purpura [TTP], screening for defective cobalamin metabolism)**.**

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Member is at least 18 years of age; **AND**
- Member is anti-aquaporin-4 (AQP4) antibody positive (lab test required); **AND**
- The diagnosis was confirmed by at least **one** of the following:
  - Optic neuritis; **OR**
  - Acute myelitis; **OR**
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; **OR**
  - Acute brainstem syndrome; **OR**
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**
- Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out; **AND**
- Member will **not** be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, or Uplizna (inebilizumab-cdon).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

PNH

- **Loading Dose:** 300 billable units (600 mg) days 1, 8, 15, and 22; then 450 billable units (900 mg) day 29
- **Maintenance Dose:** 450 billable units (900 mg) every 14 days

aHUS, gMG, MOSD

- **Loading Dose:** 450 billable units (900 mg) days 1, 8, 15, and 22; then 600 billable units (1,200 mg) day 29
- **Maintenance Dose:** 600 billable units (1,200 mg) every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SOMATULINE® DEPOT (LANREOTIDE)

HCPCS: J1930, J1932

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received a long-acting somatostatin analog within the last 4 weeks; **AND**
- Member meets indication specific criteria below:

Acromegaly

- Member's diagnosis is confirmed by one of the following:
  - Unequivocally elevated (age-adjusted) serum insulin-like growth factor-1 (IGF-1); **OR**
  - Equivocally elevated (age-adjusted) serum IGF-1 AND inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Member has documented inadequate response to surgery and/or radiotherapy or it is not an option for the member; **AND**
- Baseline GH and IGF-1 blood levels have been obtained (renewal will require reporting of current levels); **AND**
- Will not be used in combination with oral octreotide.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- Member has unresectable, locally advanced or metastatic disease; **AND**
- Member has non-functioning tumors without hormone-related symptoms; **AND**
- Member has well or moderately differentiated disease.

Carcinoid Syndrome

- Member has documented neuroendocrine tumors with a history of carcinoid syndrome (flushing and/or diarrhea); **AND**
  - Used to reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
  - Used for treatment and/or control of symptoms.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

120 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SPEVIGO® (SPESOLIMAB-SBZO)

HCPCS: J1747

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

900 billable units on days 1 and 8, then 300 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

SPINRAZA® (NUSINERSEN)

HCPCS: J2326

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member will not use in combination with other agents for SMA (e.g., onasemnogene abeparvovec-xioi, risdiplam, etc.); **AND**
- Member must have the following laboratory tests at baseline and prior to each administration: platelet count, prothrombin time, activated partial thromboplastin time, and quantitative spot urine protein testing; **AND**
- Member must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the SMN1 gene or dysfunctional mutation of the SMN1 gene; **AND**
- Member must have a diagnosis of SMA phenotype I, II, or III; **AND**
  - Member has ≤ 3 copies of the SMN2 gene (**Note**: Patients with > 3 copies of the SMN2 gene will be reviewed on a case-by-case basis); **OR**
  - Member has symptomatic disease (i.e., impaired motor function and/or delayed motor milestones); **AND**
- Baseline documentation of one or more of the following:
  - Motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), Upper Limb Module (ULM), Motor Function Measure 32 (MFM32), Revised Upper Limb Module (RULM), etc.
  - Respiratory function tests (e.g., forced vital capacity [FVC], etc.)
  - Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Member weight (for patients without a gastrostomy tube)

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

Low Dose Regimen

- 120 billable units every 14 days for three doses; then a fourth 120 billable unitloading dose 30 days after the third dose; then 120 billable units every 4 months thereafter.

High Dose Regimen

- 500 billable units loading dose followed by a second 500 billable units 14 days later; then 280 billable units every 4 months thereafter.

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

SPRAVATO® (ESKETAMINE)

HCPCS: J0013

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years old; **AND**
- Member must have a baseline assessment using any validated depression rating scale (e.g., Montgomery-Asberg Depression Rating Scale [MADRS], Hamilton Depression Rating Scale [HAM-D], Patient Health Questionnaire Depression Scale [PHQ-9], Beck Depression Inventory [BDI], Quick Inventory of Depressive Symptomatology [QIDS], etc.); **AND**
- Member has a diagnosis of major depressive disorder (MDD) according to the current version of the Diagnostic and Statistical Manual of Mental Disorders (e.g., DSM-5-TR); **AND**
- Member must not have any of the following:
  - Aneurysmal vascular disease
  - Arteriovenous malformation
  - History of intracerebral hemorrhage
  - Known hypersensitivity to ketamine; **AND**
- Member is not receiving concomitant ketamine therapy; **AND**
- Member meets indication specific criteria below:

Treatment-Resistant Depression (TRD)

- Used as monotherapy or in conjunction with an oral antidepressant; **AND**
- Member has tried psychotherapy alone or in combination with an oral antidepressant, if psychotherapy resources are available; **AND**
- Member is NOT receiving concomitant electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), vagus nerve stimulation (VNS), or deep brain stimulation (DBS); **AND**
- Member has failed a trial of at least 2 antidepressants of different classes for a duration of at least 6 weeks each with adequate adherence at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced ('Failed trial' is defined as less than or equal to 25% reduction in symptom severity using any validated depression rating scale)

Depressive Symptoms In Members With Major Depressive Disorder (MDD) With Acute Suicidal Ideation/Behavior

- Must be used in conjunction with an oral antidepressant; **AND**
  - Member is experiencing acute suicidal ideation or behavior; **OR**
  - Member has recently been discharged from a hospital in which treatment with esketamine has been initiated.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**

- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

168 billable units weekly

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

STIMUFEND® (PEGFILGRASTIM-FPGK)

HCPCS: Q5127

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

SUSTOL® (GRANISETRON EXTENDED-RELEASE)

HCPCS: J1627

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Product will be administered alongside chemotherapy in an appropriate healthcare setting (e.g., outpatient oncology infusion center, hospital outpatient department, inpatient hospital setting, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

100 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

SYFOVRE® (PEGCETACOPLAN)

HCPCS: J2781

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a baseline assessment for all the following: best corrected visual acuity (BCVA), fundus autofluorescence (FAF) imaging, and optical coherence tomography (OCT); **AND**
- Member is free of ocular and/or peri-ocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Will not be used in combination with other intravitreal complement inhibitor therapies; **AND**
- Member does not have category 5, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**
- Member has a diagnosis of Geographic Atrophy (GA) as defined by a phenotype of geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; **AND**
- Disease is secondary to age-related macular degeneration (AMD); **AND**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

30 billable units every 25 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

SYLVANT® (SILTUXIMAB)

HCPCS: J2860

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is human immunodeficiency virus (HIV) negative; **AND**
- Member is human herpesvirus-8 (HHV-8) negative; **AND**
- Member is currently free of all clinically significant active infections; **AND**
- Member will NOT receive any live vaccines during treatment with siltuximab; **AND**
- Must be used as a single agent; **AND**
- Member has a diagnosis of Multicentric Castleman's Disease (MCD).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

130 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TAKHZYRO® (LANADELUMAB-FLYO)

HCPCS: J0593

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Requested medication will be used for prophylaxis of hereditary angioedema (HAE) attacks; **AND**
- Member's diagnosis of HAE has been confirmed as C1 inhibitor (C1-INh) deficiency/dysfunction (type 1 or 2 HAE) or type 3 (normal c1-INh) as documented by one of the following:
  - C1-INh antigenic level below the lower limit of normal; **OR**
  - C1-INh functional level below the lower limit of normal; **OR**
  - Normal C4 and normal C1-INh level and function with genetic testing demonstrating the presence of a mutation specific for type 3 HAE OR a family history of angioedema together with a demonstrated lack of response to prophylactic therapy for mast cell-mediated angioedema; **AND**
- Medication is prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- One of the following:
  - Member is at least 2 years of age but younger than 6 years of age; **OR**
  - Member is at least 6 years of age; **AND**
    - Member has tried and failed the preferred product Cinryze (C1 esterase inhibitor).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TALVEY® (TALQUETAMAB-TGVS)

HCPCS: J3055

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of all step-up doses; **AND**
  - Member had an absence of unacceptable toxicity while on inpatient administration of step-up doses; **OR**
  - Provider has confirmed that the first three doses are planned for inpatient administration and will only proceed with continued treatment if the member had an absence of unacceptable toxicity to the inpatient administration of step-up doses; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection according to local guidelines; **AND**
- Member does not have active CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**
- Member has not had an allogenic stem cell transplant within the previous six (6) months or an autologous stem cell transplant within the previous twelve (12) weeks; **AND**
- Member weight and signs of oral and skin toxicity will be monitored at baseline and periodically during therapy; **AND**
- Member has a diagnosis of Multiple Myeloma; **AND**
- Member has relapsed or refractory disease; **AND**
  - Used as a single agent; **AND**
    - Member has received at least four (4) prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.25 MG)

1280 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TECARTUS® (BREXUCABTAGENE AUTOLEUCEL)

HCPCS: Q2053

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment and until immune recovery following treatment; **AND**
- Member will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Used as a single agent (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Member has not received prior CAR-T therapy; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with brexucabtagene autoleucel; **AND**
- Member meets indication specific criteria below:

Mantle Cell Lymphoma

- Member has relapsed or refractory disease; **AND**
- Used as subsequent therapy after prior covalent Bruton Tyrosine Kinase Inhibitor (BTKi) therapy; **AND**
  - Member had no response or progressive disease following second-line therapy with covalent BTKi or other continuous treatment regimens (i.e., lenalidomide and rituximab); **OR**
  - Member had partial response, no response, or progressive disease following second-line therapy with fixed-duration regimens; **OR**
  - Member has relapsed or progressive disease that is in second or greater relapse.

B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

- Member has relapsed or refractory disease; **AND**
- Member has not received other anti-CD19 therapy, (e.g., blinatumomab, tafasitamab, loncastuximab tesirine) or member previously received other anti-CD19 therapy and rebiopsy indicates CD19 positive disease; **AND**
  - Member has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Previous therapy has included tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
  - Member has Philadelphia chromosome (Ph)-negative disease.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 infusion of up to 200 million autologous anti-CD19 CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

TECELRA® (AFAMITRESGENE AUTOLEUCEL)

HCPCS: Q2057

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least ~~18~~ 12 years of age; **AND**
- Member does not have HLA-A*02:05P in either allele (i.e., heterozygous or homozygous); **AND**
- Member has not received systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion; **AND**
- Member has not received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function); **AND**
- Member does not have a history of hypersensitivity to dimethyl sulfoxide (DMSO); **AND**
- Member does not have symptomatic brain metastases including leptomeningeal disease; **AND**
- Member does not have a left ventricular ejection fraction (LVEF) less than 50%; **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member will be screened and found to be negative for Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and any other infectious agents, if clinically indicated; **AND**
- Member is HIV negative as confirmed by a negative HIV test prior to mobilization (Note: Members who have received Tecelra are likely to test false-positive on some commercial HIV nucleic acid tests for HIV due to the lentiviral vector used to make Tecelra having limited, short spans of genetic material which is identical to HIV); **AND**
- Member will be monitored for secondary malignancies periodically after treatment; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with afamitresgene autoleucel; **AND**
- Member has a diagnosis of unresectable or metastatic synovial sarcoma; **AND**
- Tumor expresses the MAGE-A4 tumor antigen; **AND**
- Member is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive; **AND**
- Used as subsequent therapy after prior treatment with doxorubicin or ifosfamide.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 dose of up to 10 billion MAGE-A4 TCR positive T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

TECENTRIQ® (ATEZOLIZUMAB) AND TECENTRIQ HYBREZA® (ATEZOLIZUMAB AND HYALURONIDASE-TQJS)

HCPCS: J9022, J9024

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified (Note: Not applicable when used as switch-therapy with subcutaneous atezolizumab); **AND**
- Subcutaneous and intravenous atezolizumab will not be used concomitantly; **AND**
- Member meets indication specific criteria below:

Non-Small Cell Lung Cancer (NSCLC)

- Used for recurrent, advanced, or metastatic disease; **AND**
  - Used as first-line therapy; **AND**
    - Used as a single agent; **AND**
      - Members who have tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and PD-L1 ≥ 50% (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **OR**
    - Used in combination with one of the following:
      - Carboplatin, paclitaxel, and bevacizumab
      - Carboplatin and albumin-bound paclitaxel; **AND**
      - Used for non-squamous disease; **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
    - Used in combination with one of the following:
      - Carboplatin, paclitaxel, and bevacizumab
      - Carboplatin and albumin-bound paclitaxel; **AND**
      - Used for non-squamous disease; **OR**
  - Used as continuation maintenance therapy in members who have achieved a tumor response or stable disease following initial therapy; **AND**
    - Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; **OR**
    - Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; **OR**
    - Used as a single agent following a first-line regimen with single agent atezolizumab; **OR**
- Used as adjuvant therapy as a single agent; **AND**

- Tumor expresses PD-L1 ≥1% as determined by an FDA-approved test or CLIA-compliant test; **AND**
  - Used following resection and previous adjuvant platinum-based chemotherapy; **AND**
    - Member has stage II to IIIA disease.

Small Cell Lung Cancer (SCLC)

- Member has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with carboplatin and etoposide; **OR**
  - Used as maintenance therapy if disease has not progressed following first-line therapy with atezolizumab (intravenous or subcutaneous), carboplatin and etoposide; **AND**
    - Used in combination with lurbinectedin.

Hepatocellular Carcinoma (HCC)

- Used in combination with bevacizumab; **AND**
  - Used as first-line therapy for unresectable or metastatic disease.

Cutaneous Melanoma

- Member has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
- Used in combination with cobimetinib and vemurafenib; **AND**
  - Member has unresectable or metastatic disease; **AND**
    - Used as first-line therapy; **OR**
    - Used as subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy; **OR**
  - Used as re-induction therapy in members who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation.

Alveolar Soft Part Sarcoma (ASPS)

- Member at least 2 years of age (Tecentriq) or member is at least 12 years of age (Tecentriq Hybreza); **AND**
- Used as a single agent.

Muscle Invasive Bladder Cancer (MIBC)

- Used as a single agent, adjuvant treatment after cystectomy; **AND**
- Member has circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***

- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (J9022: 1 BILLABLE UNIT = 10 MG; J9024: 1 BILLABLE UNIT = 5 MG)

- Tecentriq (IV): 504 billable units every 84 days
- Tecentriq Hybreza (SQ): 375 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TECVAYLI® (TECLISTAMAB-CQYV)

HCPCS: J9380

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of all step-up doses; **AND**
  - Member had an absence of unacceptable toxicity while on inpatient administration; **OR**
  - Provider has confirmed that the first three doses are planned for inpatient administration and will only proceed with continued treatment if the member had an absence of unacceptable toxicity to the inpatient administration of step-up doses; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection (e.g., herpes zoster reactivation) according to local guidelines; **AND**
- Member immunoglobulin levels will be monitored throughout treatment; **AND**
- Member does not have any of the following comorbidities:
  - Stroke
  - Seizure
  - Active CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**
- Member has not had an allogenic stem cell transplant within the previous 6 months or an autologous stem cell transplant within the previous 12 weeks; **AND**
- Member has a diagnosis of Multiple Myeloma; **AND**
  - Member has relapsed or refractory disease; **AND**
    - Used as a single agent; **AND**
      - Member has received at least four (4) prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.); **OR**
    - Used in combination with daratumumab and hyaluronidase-fihj; **AND**
      - Member has received at least one (1) prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

2448 billable units every 28 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TEPEZZA® (TEPROTUMUMAB-TRBW)

HCPCS: J3241

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology; **AND**
- Member has not had a decrease in best corrected visual acuity (BCVA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); **AND**
- Member is euthyroid [Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)]; **AND**
- Member does not have corneal decompensation that is unresponsive to medical management; **AND**
- Member does not have uncontrolled diabetes; **AND**
- Member hearing will be assessed before, during, and after treatment; **AND**
- Used as single agent therapy; **AND**
- Member has a clinical diagnosis of Thyroid Eye Disease (TED) based on characteristic clinical signs and features in the context of autoimmune thyroid disease; **AND**
  - Member has active disease; **AND**
    - Member has moderate-to-severe TED as defined by one of the following:
      - Clinical Activity Score (CAS) ≥ 4
      - severe proptosis (≥ 3 mm)
      - intermittent or constant diplopia
      - moderate or severe soft tissue involvement
      - orbital pain and/or pressure; **OR**
    - Member had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; **OR**
  - Member has inactive disease; **AND**
    - Member has a lid retraction of ≥ 2 mm; **AND**
    - Member has mild or early optic neuropathy with close clinical observation.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

150 billable units initially followed by 250 billable units every 3 weeks for 7 additional doses

LENGTH OF AUTHORIZATION

6 months for initial approval (max total of 8 infusions), not eligible for renewal

TEVIMBRA® (TISLELIZUMAB-JSGR)

HCPCS: J9329

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified; **AND**
- Member meets indication specific criteria below:

Esophageal Cancer

- Member is not a surgical candidate or has unresectable, recurrent, or metastatic disease; **AND**
  - Used as first-line therapy; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test; **AND**
    - Member has esophageal squamous cell carcinoma (ESCC); **AND**
      - Used in combination with platinum-containing chemotherapy; **OR**
  - Used as subsequent therapy after prior systemic chemotherapy; **AND**
    - Used as a single agent; **AND**
    - Member has esophageal squamous cell carcinoma (ESCC).

Gastric or Gastroesophageal Junction Adenocarcinoma

- Used in combination with platinum and fluoropyrimidine-based chemotherapy; **AND**
- Member is not a surgical candidate or has unresectable, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
- Member has HER2-negative disease; **AND**
- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

1200 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TEZSPIRE® (TEZEPELUMAB-EKKO)

HCPCS: J2356

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

Severe Asthma

- Member is at least 12 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Tezspire will not be coadministered with another monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab, mepolizumab, depemokimab-ulaa); **AND**
- Tezspire will be used as add-on maintenance treatment in members regularly receiving both of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Member is at least 12 years of age; **AND**
- Member has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Tezspire will not be coadministered with another monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, mepolizumab, dupilumab, depemokimab-ulaa); **AND**
- Member has failed an 8-week trial of intranasal corticosteroid therapy; **AND**
- Tezspire will be used in combination with intranasal corticosteroids unless unable to tolerate or is contraindicated.

RENEWAL CRITERIA

Severe Asthma

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations

- ER visits
- Unscheduled visits to a healthcare provider
- Improvement from baseline in forced expiratory volume in 1 second (FEV1).

Chronic Rhinosinusitis with Nasal Polyps

- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sinonasal outcome test-22 [SNOT-22]); **OR**
- Member has improvement in at least one of the following response criteria:
  - Reduction in nasal polyp size
  - Reduction in need for systemic corticosteroids
  - Improvement in quality of life
  - Improvement in sense of smell
  - Reduction of impact of comorbidities

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- 210 billable units every 4 weeks

Definitions

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive)**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV_1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

THYROGEN® (THYROTROPIN ALFA)

HCPCS: J3240

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of well-differentiated thyroid cancer; **AND**
  - Used as an adjunctive diagnostic test; **AND**
    - Member has had previous thyroidectomy; **OR**
  - Used as an adjunctive treatment for radioiodine ablation; **AND**
    - Member has undergone total/near-total thyroidectomy; **AND**
    - Member does not have distant metastases.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.9 MG)

1 billable unit daily for 2 doses

LENGTH OF AUTHORIZATION

2 doses for initial approval, not eligible for renewal

TIVDAK® (TISOTUMAB VEDOTIN-TFTV)

HCPCS: J9273

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has had an ophthalmic exam (i.e., visual acuity and slit lamp exam of the anterior segment of the eye, and an assessment of normal eye movement) at baseline, prior to every cycle for the first nine cycles, and as clinically indicated; **AND**
- Member has a diagnosis of Cervical Cancer; **AND**
- Used as subsequent therapy; **AND**
- Member has recurrent or metastatic disease; **AND**
- Member has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

200 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TOFIDENCE® (TOCILIZUMAB-BAVI)

HCPCS: Q5133

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Cytokine Release Syndrome:

- 3200 billable units

All other indications:

- 800 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TORISEL® (TEMSIROLIMUS)

HCPCS: J9330

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Confirmation that member does not have bilirubin >1.5 times the upper limit of normal (ULN); **AND**
- Used as a single agent; **AND**
- Member has a diagnosis of advanced Renal Cell Carcinoma.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

25 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TRASTUZUMAB - INTRAVENOUS

HCPCS: J9355, Q5112, Q5113, Q5114, Q5116, Q5117, Q5146

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test, unless otherwise specified; **AND**
- Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for 7 months after the last dose; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Member meets indication specific criteria below:

Breast Cancer

- Used as adjuvant therapy; **AND**
  - Member has ≥ T1 disease, node positive disease, or inflammatory disease (unless otherwise specified); **AND**
    - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.); with pertuzumab (pT2-3 and pN0 or pN+ ONLY); **OR**
    - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) without pertuzumab; **OR**
    - Used in combination with pertuzumab; **OR**
    - Used as a single agent; **OR**
  - Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; **AND**
    - Member has ≥ ypT0N0 or pCR disease by axillary staging; **AND**
    - Used as a single agent or in combination with pertuzumab; **OR**
- Used as neoadjuvant or preoperative therapy; **AND**
  - Member has ≥ T1c disease, node positive disease, or inflammatory disease; **AND**
  - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; **OR**
- Used for recurrent unresectable (local or regional) or metastatic disease OR inflammatory breast cancer, unless otherwise specified; **AND**
  - Used as a single agent in members who have received one or more prior chemotherapy regimens for metastatic disease; **OR**

- Used in combination with one of the following:
  - Paclitaxel as first-line therapy for metastatic disease
  - Tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib in members with hormone receptor-positive disease; **AND**
    - Member is postmenopausal; **OR**
    - Member is premenopausal and is treated with ovarian ablation/suppression; **OR**
    - Member is premenopausal and will not receive ovarian ablation/suppression (with tamoxifen ONLY); **OR**
    - Member is a male (sex assigned at birth)
  - Neratinib and fulvestrant as third-line therapy and beyond in members with HER2 activating mutations (for use in metastatic disease only); **AND**
    - Member has hormone receptor-positive, HER2 negative disease; **AND**
      - Member has already received CDK4/6 inhibitor therapy; **OR**
    - Member has triple negative disease
  - Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
  - Capecitabine and tucatinib as second-line therapy and beyond
  - Cytotoxic chemotherapy as fourth-line therapy and beyond
  - Lapatinib (without cytotoxic therapy) as fourth-line therapy and beyond
  - Pertuzumab with or without cytotoxic therapy as subsequent therapy in members previously treated with chemotherapy and trastuzumab (without pertuzumab).

Gastric, Esophageal, and Esophagogastric Junction Cancers

- Member has adenocarcinoma; **AND**
- Member is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
  - Used in combination with chemotherapy; **OR**
  - Used in combination with pembrolizumab, fluoropyrimidine- and platinum-containing chemotherapy; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**

- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy; **AND**
- Left ventricular ejection fraction (LVEF) obtained within the previous 3 months as follows:
  - LVEF is within the institutional normal limits, and has not had an absolute decrease of ≥ 16% from pre-treatment baseline; **OR**
  - LVEF is below the institutional lower limits of normal and has not had an absolute decrease of ≥ 10% from pre-treatment baseline.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

Ogivri, Kanjinti, Trazimera, Herzuma/trastuzumab-pkrb, Ontruzant, Hercessi (420 mg MDV)

- Gastric, Esophageal, and Esophagogastric Junction Cancer: 92 billable units for 1 dose then 138 billable units every 42 days
- Breast Cancer: 92 billable units for 1 dose then 69 billable units every 21 days

Herceptin (150 mg SDV)

- Gastric, Esophageal, and Esophagogastric Junction Cancer: 90 billable units for 1 dose then 150 billable units every 42 days
- Breast Cancer: 90 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TRELSTAR® (TRIPTORELIN)

HCPCS: J3315

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of advanced Prostate Cancer.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 3.75 MG)

6 billable units every 168 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TREMFYA® (GUSELKUMAB)

HCPCS: J1628

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Plaque Psoriasis and Psoriatic Arthritis

- 100 billable units at weeks 0 and 4, then every 56 days thereafter

Crohn's Disease and Ulcerative Colitis

- 400 billable units at weeks 0, 4, and 8, then 200 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TRIPTODUR® (TRIPTORELIN)

HCPCS: J3316

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have a hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analog type medications; **AND**
- Member has a diagnosis of Central Precocious Puberty (CPP); **AND**
- Member is between the ages of 2 and less than 13 years; **AND**
- Will not be used in combination with growth hormone; **AND**
- Member has onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 3.75 MG)

6 billable units every 168 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TRODELVY® (SACITUZUMAB GOVITECAN-HZIY)

HCPCS: J9317

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Members at increased risk of febrile neutropenia (including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities) will receive primary prophylaxis with a granulocyte colony stimulating factor (G-CSF) starting in the first cycle of treatment; **AND**
- Therapy will NOT be substituted for or used in combination with irinotecan; **AND**
- Members that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele will be closely monitored for adverse reactions; **AND**
- Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib, etc.) or inducers (e.g., phenytoin, carbamazepine, etc.); **AND**
- Used as a single agent; **AND**
- Member has triple-negative breast cancer [TNBC] (i.e., estrogen, progesterone, and HER2-negative); **AND**
  - Member has unresectable locally advanced disease; **AND**
    - Member was previously treated with at least two systemic therapies, at least one of them for metastatic disease; **OR**
  - Member has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
    - Member was previously treated with at least one prior therapy for metastatic disease; **OR**
- Member has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer; **AND**
  - Member has unresectable locally advanced, or metastatic disease; **AND**
    - Member was previously treated with endocrine therapy and at least two additional lines of systemic therapy for metastatic disease.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…); **OR**
- Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**

- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2.5 MG)

864 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

TROGARZO® (IBALIZUMAB-UIYK)

HCPCS: J1746

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has tried and failed at least two of the preferred HIV agents on the PDL (see HIV/AIDS agents on the PDL)

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

200 billable units once (loading dose) then 80 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TYENNE® (TOCILIZUMAB-ANOH)

HCPCS: Q5135

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents (see Cytokine and CAM Antagonists on the PDL); **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

Subcutaneous

- 162 billable units every 7 days

Intravenous

- Cytokine Release Syndrome: 3200 billable units
- All other indications: 800 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

TYSABRI® (NATALIZUMAB) AND BIOSIMILARS (TYRUKO® – NATALIZUMAB-SZTN)

HCPCS: J2323, Q5134

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

Multiple Sclerosis

- Member is at least 18 years of age; **AND**
- Member and prescriber have been enrolled in and meet the conditions of the TOUCH/REMS program; **AND**
- Member has had a JCV antibody test completed within the past 6 months and been counseled on the risks and benefits of treatment; **AND**
- Requested product will not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents; **AND**
- Member is not immunocompromised; **AND**
- Requested product will be used as single therapy; **AND**
- Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
- Member has a diagnosis of a relapsing form of MS (i.e., relapsing-remitting MS [RRMS*], active secondary progressive disease [SPMS**], or clinically isolated syndrome [CIS***]); **AND**
- Member has a documented trial and failure of **two** of the preferred Multiple Sclerosis agents (see Multiple Sclerosis on the PDL).

Crohn's Disease

- Member is at least 18 years of age; **AND**
- Member and prescriber have been enrolled in and meet the conditions of the TOUCH/REMS program; **AND**
- Member has a documented negative JCV antibody ELISA test within the past 6 months; **AND**
- Requested product will not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents; **AND**
- Member is not immunocompromised; **AND**
- Requested product will be used as single agent therapy; **AND**
- Member has moderate to severe active disease; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Member has a documented trial and failure on one oral immunosuppressive therapy for at least 3 months, unless use is contraindicated, such as corticosteroids, methotrexate, azathioprine, and/or 6-mercaptopurine; **AND**
- Member has a documented trial and failure of **two** of the preferred Cytokine and CAM antagonist agents for Crohn's Disease (see Cytokine and CAM Antagonists on the PDL).

RENEWAL CRITERIA

Multiple Sclerosis

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

Crohn's Disease

For initial renewal only:

- Member has been tapered off of corticosteroids within 6 months of starting requested product; **AND**
- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool.

Subsequent renewals:

- Member has not required additional steroid use that exceeds more than 3 months in a calendar year; **AND**
- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

- 300 billable units every 28 days

Definitions

***Definitive diagnosis of MS with a relapsing-remitting course is based upon:**

- Dissemination in space (see below) AND one or more of the following:
  - Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  - Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  - Dissemination in time (DIT) (see below)
  - Presence of lesions in at least four of five CNS anatomical locations; **OR**
- Lesions present in one CNS site (including members with 12 months or longer progression from onset) AND one or more of the following:
  - CSF positivity and CVS positivity
  - CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  - DIT (see below) and CVS positivity
  - DIT (see below) and PRL positivity

Unless contraindicated, MRI should be obtained (even if criteria are met).

Dissemination in time (development/appearance of new CNS lesions over time)

- ≥ 2 clinical attacks; **OR**
- Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR**
- A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI

Dissemination in space (development of lesions in distinct anatomical locations within the CNS; multifocal)

- MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR**
- In members with progressive disease (members with 12 months or longer progression from onset), two spinal cord lesions

****Active secondary progressive MS (SPMS) is defined as the following:**

- Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND**
- Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤ 5.5 or increase by 0.5 in patients with EDSS ≥ 6); **AND**
  - At least 1 relapse within the previous 2 years; **OR**
  - Member has gadolinium-enhancing activity **or** new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI.

*****Definitive diagnosis of CIS is based upon all of the following:**

- A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
- Neurologic symptom duration of at least 24 hours, with or without recovery
- Absence of fever or infection
- Member is not known to have multiple sclerosis

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

TZIELD® (TEPLIZUMAB-MZWV)

HCPCS: J9381

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- ~~Member is at least 1 year of age; **AND**~~
- Member has not received prior therapy with teplizumab; **AND**
- Provider will confirm that member is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member has been evaluated for the absence of active Epstein-Barr virus (EBV) or cytomegalovirus (CMV) infection; **AND**
- Member does not have any of the following laboratory indices:
  - Lymphocyte count less than 1,000 lymphocytes/µL
  - Hemoglobin less than 10 g/dL
  - Platelet count less than 150,000 platelets/µL
  - Absolute neutrophil count less than 1,500 neutrophils/µL
  - Elevated ALT or AST greater than two times the upper limit of normal (ULN)
  - Bilirubin greater than 1.5 times ULN; **AND**
- Provider will confirm that member will not receive live or live-attenuated vaccines within 8 weeks OR inactivated or mRNA vaccines within 2 weeks, prior to or during treatment; **AND**
- ~~Therapy will not be used for Type 2 Diabetes Mellitus; **AND**~~
- Provider will confirm that therapy will not be used as a disease modifying therapy in non-autoimmune dysglycemic conditions; **AND**
- Used as single agent therapy; **AND**
- Member has a confirmed diagnosis of Stage 2 type 1 diabetes (T1D); **AND**
  - Confirmation that the member's diagnosis is of autoimmune origin and does not suggest insulin resistance due to obesity, type 2 diabetes or dysglycemia due to other forms of diabetes (including, but not limited to, genetic forms of diabetes, maturity-onset diabetes of the young [MODY], latent autoimmune diabetes in adults [LADA], or diabetes secondary to medications or surgery); **AND**
  - Member will receive treatment to delay the onset of Stage 3 type 1 diabetes; **AND**
    - For members ≥ 1 year of age to < 18 years of age:
      - Confirmation of two or more of the following pancreatic islet cell autoantibodies:
        - Glutamic acid decarboxylase 65 (GAD65) autoantibodies
        - Insulin autoantibody (IAA)
        - Insulinoma-associated antigen 2 autoantibody (IA-2A)
        - Zinc transporter 8 (ZnT8A) autoantibody
        - Islet cell autoantibody (ICA); **AND**

- Confirmation of dysglycemia without overt hyperglycemia using an oral glucose tolerance test (if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate) defined as one of the following:
  - Fasting glucose 100-125 mg/dL
  - 2-hour postprandial plasma glucose 140-199 mg/dL
  - An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL
  - A1C 5.7-6.4% or ≥ 10% increase in A1C
- For members ≥ 18 years of age to < 45 years of age:
  - Confirmation of dysglycemia without overt hyperglycemia using an OGTT (if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate) defined as one of the following:
    - Fasting glucose 100-125 mg/dL
    - 2-hour postprandial plasma glucose 140-199 mg/dL
    - An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL
    - A1C 5.7-6.4% or ≥ 10% increase in A1C; **OR**

- Member has been recently (i.e., within the previous 8 weeks) diagnosed with Stage 3 type 1 diabetes (T1D); **AND**
  - Member is 8 to 17 years of age; **AND**
  - Member will receive treatment to delay the decline in endogenous insulin production based on confirmation of BOTH of the following:
    - Confirmation of at least one of the following pancreatic islet cell autoantibodies:
      - Glutamic acid decarboxylase 65 (GAD65) autoantibodies
      - Islet antigen 2 (IA-2) autoantibodies
      - Zinc transporter 8 (ZnT8) autoantibodies
      - Islet cell cytoplasmic autoantibodies (ICA)
      - Insulin autoantibodies (if testing obtained within the first 14 days of insulin treatment); **AND**
    - Peak C-peptide ≥0.2 pmol/mL on a mixed-meal tolerance test (if a mixed meal tolerance test is not available, an alternative method for measuring peak C-peptide ≥0.2 pmol/mL may be appropriate).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MCG)

Stage 2 Type 1 Diabetes

- 5600 billable units over a 14-day course of therapy

Stage 3 Type 1 Diabetes

- 4800 billable units over a 12-day course of therapy for a total of 2 treatment courses administered 6 months apart

LENGTH OF AUTHORIZATION

Stage 2 Type 1 Diabetes

- 14 doses for initial approval, not eligible for renewal

Stage 3 Type 1 Diabetes

- 12 doses for initial approval, may be renewed for one additional treatment course for a total of 12 doses

UDENYCA® (PEGFILGRASTIM-CBQV)

HCPCS: Q5111

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ULTOMIRIS® (RAVULIZUMAB-CWVZ)

HCPCS: J1303

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is free of *Neisseria meningitidis* infection; **AND**
- Member will **not** be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), or Epysqli (eculizumab-aagh); **AND**
- Member meets the indication specific criteria below:

Generalized Myasthenia Gravis (gMG)

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of generalized Myasthenia Gravis (gMG) **and all** of the following:
  - Member has a positive serological test for anti-AChR antibodies (medical records required); **AND**
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - Member has a MG-Activities of Daily Living total score of greater than or equal to 6; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
  - Member will **not** be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
- Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Member is at least 1 month of age; **AND**
- Member has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) **and all** of the following:
  - The diagnosis was confirmed by flow cytometry with at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (lab tests required); **AND**

- Member will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Fabhalta (iptacopan), or Piasky (crovalimab-akkz).

Hemolytic Uremic Syndrome (aHUS)

- Member is at least 1 month of age; **AND**
- Member has a diagnosis of atypical Hemolytic Uremic Syndrome (aHUS) **and all** of the following:
  - Member is negative for Shiga toxin-producing E. coli (STEC); **AND**
  - The diagnosis was confirmed by **one** of the following: (medical records required)
    - Genetic mutation (e.g., CFH, CD46, CFI, C3, CFB, THBD, CFHR1, CFHR3, CFHR5); **OR**
    - Antibodies to complement factors; **OR**
    - A differential diagnosis of complement-mediated HUS has been demonstrated (i.e., screening for Shiga toxin-producing E. coli [STEC] for STEC-HUS, pneumococcal culture of blood/sputum/cerebrospinal or pleural fluid for pneumococcal-associated HUS, ADAMTS13 less than 10% activity for thrombotic thrombocytopenic purpura [TTP], screening for defective cobalamin metabolism).

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Member is at least 18 years of age; **AND**
- Member is anti-aquaporin-4 (AQP4) antibody positive (lab test required); **AND**
- The diagnosis was confirmed by at least **one** of the following:
  - Optic neuritis; **OR**
  - Acute myelitis; **OR**
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; **OR**
  - Acute brainstem syndrome; **OR**
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**
- Member had at least one discrete clinical attack of CNS symptoms; **AND**
- Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out; **AND**
- Member will **not** be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, or Uplizna (inebilizumab-cdon).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

300 billable units on Day 0 followed by 360 billable units on Day 14 and every 8 weeks thereafter

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

UNITUXIN® (DINUTUXIMAB)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is less than 18 years of age; **AND**
- Will not be used in combination with other GD2-binding monoclonal antibodies; **AND**
- Member has a diagnosis of High-Risk Neuroblastoma; **AND**
- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim), interleukin-2 [IL-2] (e.g., aldesleukin), and 13-cis-retinoic acid (RA) (e.g., isotretinoin); **AND**
  - Member had at least partial response to first-line multiagent, multimodality therapy.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS

52.5 mg per day for four doses every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

UNLOXCYT™ (COSIBELIMAB-IPDL)

HCPCS: J9275

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified Δ; **AND**
- Member has locally advanced, satellitosis/in-transit metastasis, or metastatic cutaneous squamous cell carcinoma (cSCC); **AND**
- Member is not a candidate for curative surgery or curative radiation; **AND**
- Used as a single agent

Δ Notes:

- Members responding to therapy who relapse at least 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Members previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Members who complete adjuvant therapy and progress at least 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

600 billable units every 3 weeks

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

UPLIZNA® (INEBILIZUMAB-CDON)

HCPCS: J1823

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member meets FDA approved age and indication; **AND**
- Documentation of medical necessity as well as evidence that the member has met the criteria outlined in PDL Appendix A has been provided.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units on days 1 and 15 then every 6 months thereafter

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

VABYSMO® (FARICIMAB-SVOA)

HCPCS: J2777

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections; **AND**
- Member does not have active intraocular inflammation; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
  - Diabetic Macular Edema (DME)
  - Macular Edema following Retinal Vein Occlusion (RVO).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

120 billable units every 28 days

LENGTH OF AUTHORIZATION

Macular Edema following Retinal Vein Occlusion (RVO)

- 6 months for initial approval, not eligible for renewal

All other indications

- 12 months for initial approval, 12 months for renewal

VECTIBIX® (PANITUMUMAB)

HCPCS: J9303

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of Colorectal Cancer; **AND**
- Member has not been previously treated with cetuximab or panitumumab; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**
  - Member has both KRAS and NRAS mutation negative (wild-type) and BRAF V600E negative (wild-type) disease as determined by an FDA or CLIA-compliant test; **AND**
    - Used as primary treatment for metastatic or unresectable (or medically inoperable) disease; **AND**
      - Used in combination with FOLFOX; **OR**
    - Used as subsequent therapy for advanced or metastatic disease; **AND**
      - Used as a single agent; **AND**
        - Member has fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease; **OR**
        - Member has irinotecan-intolerant disease; **OR**
  - Member has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Used as subsequent therapy; **AND**
      - Used for metastatic disease; **AND**
        - Used in combination with sotorasib; **AND**
        - Member has received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

70 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

VEOPOZ® (POZELIMAB-BBFG)

HCPCS: J9376

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Members must be administered a meningococcal vaccine (for serogroups A, C, W and Y, and serogroup B) according to current ACIP recommendations at least two weeks prior to initiation of therapy and will continue to be revaccinated in accordance with ACIP recommendations (If urgent Veopoz therapy is indicated in a member who is not up-to-date with meningococcal vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide patients with antibacterial drug prophylaxis); **AND**
- Member must be administered vaccinations for the prevention of Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) infections according to ACIP guidelines; **AND**
- Will not be used in combination with other complement therapies; **AND**
- Member does not have an unresolved *Neisseria meningitidis* infection; **AND**
- Member will avoid concomitant therapy with intravenous immunoglobulin, if therapy is unavoidable, the member will be monitored closely for adverse reactions and/or worsening of disease symptoms; **AND**
- Member has a confirmed clinical diagnosis of CD55-deficient protein-losing enteropathy (PLE, also known as CHAPLE) evidenced by biallelic CD55 loss-of-function mutation detected by genotype analysis; **AND**
- Member has active disease as defined as hypoalbuminemia (serum albumin concentration of ≤3.2 g/dL) with one or more of the following signs or symptoms attributed to CD55-deficient PLE within the last six months:
  - Abdominal pain
  - Diarrhea
  - Peripheral edema
  - Facial edema.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

3200 billable units on Day 1 then 3200 billable units on Day 8 and every 28 days thereafter

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

VIDAZA® (AZACITIDINE)

HCPCS: J9025

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member does not have advanced malignant hepatic tumors; **AND**
- Member does not have a hypersensitivity to mannitol; **AND**
- One of the following:
  - Member has a diagnosis of Myelodysplastic Syndrome (MDS); **AND**
    - Member is at least 18 years of age; **OR**
  - Member has a diagnosis of Juvenile Myelomonocytic Leukemia (JMML); **AND**
    - Member is at least 1 month to < 18 years of age; **AND**
    - Used as a single agent therapy for newly diagnosed disease.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

2100 billable units every 28 days

LENGTH OF AUTHORIZATION

Juvenile Myelomonocytic Leukemia

- 6 months for initial approval, not eligible for renewal

All Other Indications

- 6 months for initial approval, 6 months for renewal

VILTEPSO® (VILTOLARSEN)

HCPCS: J1427

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a confirmed diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Member has been on a stable dose of corticosteroids (unless contraindicated or intolerant); **AND**
- Member will not be using any other exon skipping agents for DMD.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

3700 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

VPRIV® (VELAGLUCERASE ALFA)

HCPCS: J3385

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 4 years of age; **AND**
- Used as a single agent; **AND**
- Member has a documented diagnosis of Type 1 Gaucher Disease confirmed by one of the following:
  - Significantly reduced or absent glucocerebrosidase enzyme activity as measured by a beta-glucosidase leukocyte (BGL) test
  - Detection of mutations in the glucocerebrosidase (GBA) gene; **AND**
- Member's disease results in one or more of the following:
  - Anemia-related symptoms [i.e., blood transfusion dependency and/or hemoglobin ≤ 11 g/dL (women and children) or ≤ 12 g/dL (men)]
  - Thrombocytopenia (platelet count ≤ 120,000/mm3)
  - Hepatomegaly or splenomegaly
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.)
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, abdominal distension, diminished quality of life, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 100 UNITS)

72 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

VYALEV™ (FOSCARBIDOPA/FOSLEVODOPA)

HCPCS: J7356

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of levodopa-responsive idiopathic Parkinson's disease with motor fluctuations; **AND**
- Member is currently taking at least 400 mg per day of levodopa equivalents; **AND**
- Member's motor fluctuations are inadequately controlled with carbidopa/levodopa therapy; **AND**
- Member has a minimum daily average "off" time of 2.5 hours per day.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = FOSCARBIDOPA 0.25 MG/FOSLEVODOPA 5 MG)

705 billable units per day

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

VYEPTI® (EPTINEZUMAB-JMMR)

HCPCS: J3032

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Prescriber has assessed baseline disease severity utilizing an objective measure/tool (e.g., International Classification of Headache Disorders [ICHD-III], Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Member is at least 18 years of age; **AND**
- Member is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy); **AND**
- Member has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for more than 3 months; **AND**
  - Member has had at least five attacks with features consistent with migraine (with and/or without aura); **AND**
  - On at least 8 days per month for more than 3 months:
    - Headaches have characteristics and symptoms consistent with migraine; **OR**
    - Member suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
  - Member has failed at least an 8-week trial of any two oral medications for the prevention of migraines (e.g., antidepressants, beta blockers, antiepileptics) prior to initiation of eptinezumab; **AND**
  - Member had an inadequate response (or unable to tolerate) a minimum trial of at least two preferred self-injectable CGRP options; **OR**
- Member has diagnosis of frequent episodic migraines defined as at least 5 headache attacks lasting 4–72 hours (when untreated or unsuccessfully treated); **AND**
  - Headaches have characteristics and symptoms consistent with migraine without aura; **AND**
  - Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Vyepti will not be used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab, galcanezumab, fremanezumab, atogepant, rimegepant).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member has experienced a clinical response as evidenced by:
  - Reduction in mean monthly headache days (MHD) of at least moderate severity of at least 50% relative to the pretreatment baseline (diary documentation or medical professional attestation); **OR**

- A clinically meaningful improvement in any of the following validated migraine-specific patient-reported outcome measures:
  - Reduction of at least 5 points when baseline score is 11–20 **or** reduction of at least 30% when baseline score is more than 20 in the MIDAS (Migraine Disability Assessment) scores; **OR**
  - Reduction of at least 5 points in the MPFID (Migraine Physical Function Impact Diary) score; **OR**
  - Reduction of at least 5 points in the HIT-6 (Headache Impact Test) score.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

300 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

VYJUVEK® (BEREMAGENE GEPERPAVEC-SVDT)

HCPCS: J3401

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has not received a skin graft in the area to be treated within the prior 3 months; **AND**
- Member has a diagnosis of dystrophic epidermolysis bullosa (DEB) as established by detection of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing; **AND**
- Will not be used concurrently in the same wound with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, etc.) (**Note**: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.); **AND**
- Member has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected.

RENEWAL CRITERIA

- Member continues to meet the indication-specific relevant criteria identified above; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: any severe medication reactions warranting therapy discontinuation, etc.; **AND**
- Disease response with treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections, etc., as attested by his/her physician; **AND**
- Member requires continued treatment due to new or existing open wounds.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 ML)

25 billable units every 7 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

VYLOY® (ZOLBETUXIMAB-CLZB)

HCPCS: J1326

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is not experiencing Grade 2 or greater nausea and/or vomiting prior to the first infusion; **AND**
- Member does not have a complete or partial gastric outlet syndrome; **AND**
- Member does not have a history of central nervous system metastases; **AND**
- Member is not a surgical candidate or has locally advanced unresectable, recurrent, or metastatic adenocarcinoma; **AND**
- Used as first-line therapy; **AND**
- Member has claudin (CLDN) 18.2-positive (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining) disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Used in combination with a fluoropyrimidine- and platinum-containing chemotherapy-based regimen.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

1500 billable units every 42 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

VYONDYS 53® (GOLODIRSEN)

HCPCS: J1429

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has a confirmed diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Member has been on a stable dose of corticosteroids (unless contraindicated or intolerant); **AND**
- Member will not be using any other exon skipping agents for DMD.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 10 MG)

1400 billable units every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

VYVGART® (EFGARTIGIMOD ALFA-FCAB)

HCPCS: J9332

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of generalized Myasthenia Gravis (gMG) **and all** of the following:
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - Member has a MG-Activities of Daily Living total score of greater than or equal to 5; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
  - Member will **not** be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
  - **One** of the following:
    - Member has tried self-administered Vyvgart Hytrulo; **OR**
    - There is support for use of a provider-administered product over the self-administered product; **AND**
  - Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

600 billable units weekly for four doses per 50 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

VYVGART® HYTRULO (EFGARTIGIMOD ALFA-FCAB AND HYALURONIDASE-GVFC)

HCPCS: J9334

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- One of the following:
  - Member will be self-administering Vyvgart Hytrulo; **OR**
  - Member has tried self-administered Vyvgart Hytrulo; **OR**
  - There is support for use of a provider-administered product over the self-administered product; **AND**
- Member meets indication specific criteria below:

Generalized Myasthenia Gravis (gMG)

- Member has a diagnosis of gMG **and all** of the following:
  - Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
  - Member has a MG-Activities of Daily Living total score of greater than or equal to 5; **AND**
  - **One** of the following:
    - Member has tried and had an inadequate response after an adequate trial to at least **two** immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
    - Member has an intolerance or hypersensitivity to at least **two** immunosuppressive therapies; **OR**
    - Member has tried and had an inadequate response after an adequate trial to treatment to at least **one** immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **and one** of the following:
      - Member required chronic intravenous immunoglobulin (IVIG); **OR**
      - Member required chronic plasmapheresis/plasma exchange; **AND**
  - Member will **not** be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
  - Must be prescribed by, or in consultation with, a neurologist or other specialist in myasthenia gravis.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Member has a diagnosis of CIDP **and all** of the following:
  - Member's disease course is progressive or relapsing and remitting for at least 2 months; **AND**
  - Member has progressive or relapsing motor sensory impairment of more than one limb; **AND**
  - Member has electrodiagnostic findings indicating demyelination with at least ONE of the following:

- Prolonged distal motor latency in at least 2 motor nerves
- Reduced motor conduction velocity in at least 2 motor nerves
- Prolonged F-wave latency in at least 2 motor nerves
- Absent F-wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
- Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here
- Abnormal temporal dispersion conduction in at least 2 motor nerves
- Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **AND**

– Member has tried and had an inadequate response to at least a 3-month trial of ONE standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange), unless contraindicated or intolerant; **AND**

– Must be prescribed by, or in consultation with, a neurologist or other specialist in CIDP.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

Chronic Inflammatory Demyelinating Polyneuropathy

- 504 billable units weekly

Generalized Myasthenia Gravis

- 504 billable units weekly for four doses per 56 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

VYXEOS® (DAUNORUBICIN AND CYTARABINE - LIPOSOME)

HCPCS: J9153

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 1 year of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits and will be reassessed prior to consolidation and as clinically required; **AND**
- Cumulative lifetime anthracycline dose does not exceed 550 mg/m2 (or 400 mg/m2 in members who received radiation to the mediastinum); **AND**
- Will not be used in combination with other chemotherapy; **AND**
- Member has therapy-related acute myeloid leukemia (t-AML) OR cytogenetic changes consistent with MDS (previously classified as AML-MRC); **AND**
  - Used as induction therapy for newly diagnosed disease; **OR**
  - Used as re-induction therapy after cytarabine-based induction therapy; **OR**
  - Used as consolidation therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG DAUNORUBICIN AND 2.27 MG CYTARABINE)

1012 billable units every 155 days

LENGTH OF AUTHORIZATION

6 months for initial approval, not eligible for renewal.

WAINUA® (EPLONTERSEN)

HCPCS: N/A

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Prescribed by, or in consultation with, a specialist in the area of the member's diagnosis; **AND**
- Member is at least 18 years of age; **AND**
- Member has a confirmed diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy); **AND**
- Member has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability); **AND**
- Member will avoid using this in combination with other transthyretin reducing or stabilizing agents (e.g., acoramidis, inotersen, tafamidis, patisiran, or vutrisiran); **AND**
- Prescriber will supplement vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) occur; **AND**
- Member has not received a liver transplant.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member continues to experience clinical benefit from the requested treatment; **AND**
- Member has an absence of unacceptable toxicity from the drug.

QUANTITY LIMITS

45 mg every 28 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

XENPOZYME® (OLIPUDASE ALFA)

HCPCS: J0218

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Females of reproductive potential will have pregnancy status verified prior to start of therapy and will use effective contraception during treatment and for 14 days after the last dose if therapy is discontinued; **AND**
- Member has documented baseline measures of at least one of the following (necessary for renewal):
  - Percent predicted diffusion capacity of the lungs for carbon monoxide (DLco) or other age-appropriate pulmonary function testing
  - Spleen and/or liver volume
  - Plasma lyso-sphingomyelin
  - Platelet count
  - Mean height Z-score and/or skeletal maturation (pediatric patients only); **AND**
- Will not be used in combination with Aqneursa (levacetylleucine) or Miplyffa (arimoclomol); **AND**
- Documented baseline transaminase (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) levels within 1 month prior to treatment initiation, within 72 hours prior to any infusion during dose escalation, and periodically throughout therapy; **AND**
- Therapy will be used to treat non-central nervous system manifestations of disease and member does not have severe, irreversible cognitive impairment; **AND**
- Member has a definitive diagnosis of Acid Sphingomyelinase Deficiency (ASMD) as confirmed by the following:
  - Detection of biallelic pathogenic mutations in the SMPD1 gene by molecular genetic testing; **OR**
  - Deficiency of acid sphingomyelinase enzyme activity <10% of controls as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

344 billable units every 14 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal.

XEOMIN® (INCOBOTULINUMTOXINA)

HCPCS: J0588

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Member does not have any of the following:
  - Any disorders which may contribute to respiratory or swallowing difficulty
  - Hypersensitivity to any botulinum toxin product
  - Active infection at the proposed injection site; **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**
- Member meets indication specific criteria below:

Cervical Dystonia

- Member has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
  - Member has sustained head tilt; **OR**
  - Member has abnormal posturing with limited range of motion in the neck.

Blepharospasms

- Member has a diagnosis of Blepharospasm.

Spastic Conditions

- Member has one of the following:
  - Upper Limb spasticity in adults; **OR**
  - Pediatric upper limb spasticity in members aged 2 years to 17 years of age~~, excluding spasticity caused by cerebral palsy.~~

Chronic Sialorrhea

- Member has a history of troublesome sialorrhea for at least a 3 month period; **AND**
  - Member has Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury; **OR**
  - Member has cerebral palsy, other genetic or congenital disorders, or traumatic brain injury; **AND**
    - Member is at least 2 years of age.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 UNIT)

400 billable units every 84 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal.

XIAFLEX® (COLLAGENASE)

HCPCS: J0775

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member meets indication specific criteria below:

Dupuytren's Contracture

- Member has a palpable cord; **AND**
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint; **AND**
- Documentation of a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top; **AND**
- Member has not received a surgical treatment (e.g., fasciectomy, fasciotomy) on the selected joint within 90 days before the first injection; **AND**
- Documentation that the flexion deformity results in functional limitations.

Peyronie's Disease

- Member has a palpable plaque on penis; **AND**
- Member has stable disease with penis curvature deformity of > 30° and < 90°; **AND**
- Member has intact erectile function (with or without use of medications); **AND**
- Member does not have a ventral curvature deformity, an isolated hourglass deformity, or a calcified plaque; **AND**
- Plaque(s) do not involve the penile urethra; **AND**
- Will be used in combination with penile modeling procedures.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.01 MG)

180 billable units every 28 days

LENGTH OF AUTHORIZATION

Dupuytren's Contracture

- 3 months for initial approval, 3 months for renewal (max of 3 injections per joint/cord)

Peyronie's Disease

- 6 weeks for initial approval, 6 weeks for renewal (max of 4 total treatment cycles for each plaque)

XIPERE® (TRIAMCINOLONE ACETONIDE INJECTABLE SUSPENSION)

HCPCS: J3299

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections (including active epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella, mycobacterial infections and fungal diseases, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member does not have untreated intraocular pressure or uncontrolled glaucoma; **AND**
- Member has macular edema related to a diagnosis of non-infectious uveitis (pan, anterior, intermediate, and/or posterior).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

72 billable units every 12 weeks

LENGTH OF AUTHORIZATION

12 weeks for initial approval, 12 weeks for renewal

XOLAIR® (OMALIZUMAB)

HCPCS: J2357, Q5154

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

Severe Asthma

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of severe* asthma; **AND**
- Member has a positive skin test or in vitro reactivity to a perennial aero-allergen; **AND**
- Member weighs between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
- Member has a serum total IgE level, measured before the start of treatment, of either:
  - At least 30 IU/mL and up to 700 IU/mL in members age at least 12 years; **OR**
  - At least 30 IU/mL and up to 1300 IU/mL in members age 6 to less than 12 years; **AND**
- Coadministration with another monoclonal antibody will be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Xolair will be used as add-on maintenance treatment for members regularly receiving both of the following:
  - Medium- to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Member must have two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization; **AND**
- Member must have at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to a healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1).

Chronic idiopathic urticaria/chronic spontaneous urticaria

- Member is at least 12 years of age; **AND**
- Other causes of the member's condition have been ruled out (e.g., allergic urticaria); **AND**
- Coadministration with another monoclonal antibody will be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member is avoiding triggers; **AND**
- Member has a documented baseline score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL); **AND**

- Member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product; **AND**
- Member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of at least one of the following:
  - Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine
  - Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast)
  - Add-on therapy with another H1-antihistamine
  - Add-on therapy with a H2-antagonist (e.g., ranitidine, famotidine).

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- Member is at least 18 years of age; **AND**
- Member has failed at least 8 weeks of intranasal corticosteroid therapy; **AND**
- Coadministration with another monoclonal antibody will be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Member has at least three of the following indicators for biologic treatment:
  - Member has evidence of type 2 inflammation (e.g., tissue eosinophils ≥ 10/hpf, blood eosinophils ≥ 150 cells/µL, or total IgE ≥ 100 IU/mL)
  - Member has required at least two courses of systemic corticosteroids per year or more than 3 months of low dose corticosteroids, unless contraindicated
  - Disease significantly impairs the member's quality of life
  - Member has experienced significant loss of smell
  - Member has a comorbid diagnosis of asthma; **AND**
- Member does not have any of the following:
  - Antrochoanal polyps
  - Nasal septal deviation that would occlude at least one nostril
  - Disease with lack of signs of type 2 inflammation
  - Cystic fibrosis
  - Mucoceles; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis); **AND**
- Physician has assessed baseline disease severity utilizing an objective measuring tool; **AND**
- Xolair will be used in combination with intranasal corticosteroids unless unable to tolerate or is contraindicated

IgE-food mediated allergy

- Member is 1 year of age or older; **AND**
- Member must have a diagnosis of food allergy; **AND**
- Coadministration with another monoclonal antibody will be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko, depemokimab-ulaa); **AND**
- Prescribed by, or in consultation with, an allergist or immunologist; **AND**
- Member has a positive skin prick test under a drop of allergen extract; **OR**

- Member has a positive IgE screening to identified foods; **AND**
- Member will continue to practice allergen avoidance.

RENEWAL CRITERIA

Severe asthma

- Member has experienced improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Hospitalizations
  - ER visits
  - Unscheduled visits to a healthcare provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

Chronic idiopathic urticaria/chronic spontaneous urticaria

- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline as documented by an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL).

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- Member has experienced a disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sinonasal outcome test-22 [SNOT-22]); **OR**
- Member had an improvement in at least one of the following response criteria:
  - Reduction in nasal polyp size
  - Reduction in need for systemic corticosteroids
  - Improvement in quality of life
  - Improvement in sense of smell
  - Reduction of impact of comorbidities

IgE-food mediated allergy

- Member is experiencing a clinical response and improvement as attested by the prescriber.

QUANTITY LIMITS (1 BILLABLE UNIT = 5 MG)

Severe Asthma

- 75 billable units every 14 days

CRSwNP and IgE-Mediated Food Allergy

- 120 billable units every 14 days

All other indications

- 60 billable units every 28 days

Definitions

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV_1) less than 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

YARTEMLEA® (NARSOPLIMAB-WUUG)

HCPCS: J1289

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 2 years of age; **AND**
- Member will be monitored closely for signs and symptoms of infection during therapy with narsoplimab and treated promptly if infection occurs; **AND**
- Member does not have a positive direct Coombs test; **AND**
- Member does not have Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS); **AND**
- Member is post-hematopoietic stem cell transplant (HSCT); **AND**
- Member has a confirmed diagnosis of Transplant Associated-Thrombotic Microangiopathy (TA-TMA) based on all of the following:
  - Platelet count less than 150,000/µL; **AND**
  - Evidence of microangiopathic hemolysis (i.e., presence of schistocytes, serum lactate dehydrogenase [LDH] greater than the upper limit of normal [ULN] and/or haptoglobin less than the lower limit of normal [LLN]); **AND**
  - Renal dysfunction.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

370 mg twice weekly (740 mg every 7 days)

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

YERVOY® (IPILIMUMAB)

HCPCS: J9228

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age, unless otherwise indicated; **AND**
- Member meets indication specific criteria below:

Colorectal Cancer (CRC)

- Member is at least 12 years of age; **AND**
- Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used in combination with nivolumab; **AND**
  - Used as primary/initial treatment for unresectable or medically inoperable, recurrent, advanced, or metastatic disease; **OR**
  - Used as subsequent therapy for unresectable or medically inoperable, advanced, or metastatic disease; **OR**
  - Used as neoadjuvant therapy for advanced or metastatic disease.

Esophageal Cancer

- Used in combination with nivolumab; **AND**
  - Used as first-line therapy; **AND**
    - Member has squamous cell carcinoma; **AND**
      - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
        - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test.

Hepatocellular Carcinoma (HCC)

- Used in combination with nivolumab; **AND**
  - Used as first-line therapy; **AND**
    - Member has unresectable or metastatic disease; **OR**
  - Used as subsequent therapy; **AND**
    - Member was previously treated with sorafenib; **AND**
    - Member has unresectable or metastatic disease.

Renal Cell Carcinoma (RCC)

- Used in combination with nivolumab for clear cell histology; **AND**
  - Used as first-line therapy; **AND**
    - Member has poor or intermediate risk advanced disease.

Pleural Mesothelioma (PM)

- Used in combination with nivolumab; **AND**
  - Used as first-line therapy; **AND**
  - Member has unresectable malignant disease.

Cutaneous Melanoma

- Used as first-line therapy for unresectable or metastatic disease; **AND**
  - Member is at least 12 years of age; **AND**
  - Used as a single agent or in combination with nivolumab; **OR**
- Used as adjuvant treatment; **AND**
  - Used as a single agent; **AND**
    - Member has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy.

Non-Small Cell Lung Cancer (NSCLC)

- Used for recurrent, advanced, or metastatic disease; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Members with tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive); **OR**
      - Members who are positive for one of the following biomarkers: EGFR exon 20 insertion mutation, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **AND**
    - Used in combination with one of the following:
      - Nivolumab; **OR**
      - Nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

350 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

YESCARTA® (AXICABTAGENE CILOLEUCEL)

HCPCS: Q2041

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during axicabtagene ciloleucel treatment and until immune recovery following treatment; **AND**
- Member will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Member has not received prior CAR-T therapy; **AND**
- Member has not received other anti-CD19 therapy (e.g., blinatumomab, tafasitamab, loncastuximab tesirine, etc.) **or** member previously received other anti-CD19 therapy and rebiopsy indicates CD19 positive disease **or** member has residual tumor activity; **AND**
- Used as a single agent (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Member does not have primary central nervous system lymphoma; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with axicabtagene ciloleucel; **AND**
- Member has large b-cell lymphoma; **AND**
  - Disease is refractory to first-line chemoimmunotherapy; **OR**
  - Disease has relapsed within 12 months of first-line chemoimmunotherapy; **OR**
- Member has large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma; **AND**
  - Disease is relapsed or refractory after two or more lines of systemic therapy; **OR**
- Member has follicular lymphoma; **AND**
  - Disease is relapsed or refractory after two or more lines of systemic therapy

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 infusion of up to 200 million autologous anti-CD19 CAR-positive viable T-cells)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

YONDELIS® (TRABECTEDIN)

HCPCS: J9352

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Member has a diagnosis of liposarcoma or leiomyosarcoma; **AND**
  - Used for unresectable or metastatic disease after an anthracycline-containing regimen (e.g., doxorubicin, liposomal doxorubicin, epirubicin, etc.).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

40 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

YUTIQ® (FLUOCINOLONE ACETONIDE IMPLANT)

HCPCS: J7314

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member is free of ocular and/or periocular infections (including active epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella, mycobacterial infections and fungal diseases, etc.); **AND**
- Member has not received a sustained-release corticosteroid in the same eye; **AND**
- Member does not have a torn or ruptured posterior lens capsule; **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Member's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Member has a diagnosis of Chronic Noninfectious Uveitis Affecting the Posterior Segment of the Eye; **AND**
- Member has had chronic disease for at least one year; **AND**
- Other causes of uveitis have been ruled out (e.g., infection, malignancy, etc.).

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.01 MG)

36 billable units every 36 months

LENGTH OF AUTHORIZATION

1 implant per eye every 36 months for initial approval, 1 implant per eye every 36 months for renewal

ZALTRAP® (ZIV-AFLIBERCEPT)

HCPCS: J9400

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have recent history of severe hemorrhage; **AND**
- Ziv-aflibercept will be not administered for at least 4 weeks following major surgery; **AND**
- Member does not have a surgical wound that has not fully healed; **AND**
- Member has metastatic Colorectal Cancer (CRC) that is resistant to or has progressed following an oxaliplatin-containing regimen (e.g., FOLFOX, CapeOX); **AND**
  - Used in combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan).

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

500 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ZARXIO® (FILGRASTIM-SNDZ)

HCPCS: Q5101

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MCG)

1560 billable units per day

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ZEPZELCA® (LURBINECTEDIN)

HCPCS: J9223

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a diagnosis of Small Cell Lung Cancer; **AND**
  - Used in combination with atezolizumab (intravenous or subcutaneous) as maintenance therapy; **AND**
    - Disease has not progressed after first-line therapy with atezolizumab (intravenous or subcutaneous), carboplatin, and etoposide; **AND**
    - Member has extensive stage disease (ES-SCLC); **OR**
  - Used as a single agent; **AND**
    - Used as subsequent systemic therapy if not previously used for progression or relapse.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.1 MG)

80 billable units every 21 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL)

HCPCS: J3389

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 6 years of age; **AND**
- Member does not have severe hypersensitivity (i.e., anaphylaxis) to vancomycin or amikacin; **AND**
- Will not be used concurrently, in the same wound, with another disease-modifying therapeutic agent indicated for DEB (e.g., birch triterpenes, beremagene geperpavec etc.) (NOTE: this does not include disease/wound management incidentals like topicals, dressings, antibiotics, etc.); **AND**
- Member does not show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated; **AND**
- Member has a diagnosis of recessive dystrophic epidermolysis bullosa as established by detection of biallelic mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular genetic testing (Note: If unable to confirm a biallelic mutation, confirmation that BOTH parents do not have any evidence of dominant disease is also acceptable); **AND**
- Member has cutaneous wound(s) which are adequate for treatment (e.g., stage 2 wounds that have an area of at least 20 cm^2) and have been present for at least 6 months.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member shows disease response to treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections, etc., as attested by his/her physician; **AND**
- Member requires treatment in a new wound area due to new expansion of pre-existing wounds previously treated with Zevaskyn, or development of new (de novo), open wounds.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 treatment of up to twelve C7-expressing cellular sheets for each surgical session)

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal.

ZIEXTENZO® (PEGFILGRASTIM-BMEZ)

HCPCS: Q5120

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member has an FDA approved indication and one of the following:
  - Member's age is within FDA labeling for the requested indication; **OR**
  - Provider has included information in support of using the requested agent for the member's age for the requested indication; **OR**
- Provider has included clinical evidence that supports medical necessity of the use of the requested medication for indications supported by compendia (Compendia allowed: DrugDex 1, 2a or 2b level of evidence, NCCN 1, 2a or 2b recommended use.)]; **AND**
- Member must have tried and failed two preferred agents in the Colony Stimulating Factors class on the PDL, where applicable for the requested product's intended use.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.5 MG)

Acute Radiation Exposure

- 12 billable units weekly for 2 doses

All other indications

- 12 billable units per 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 12 months for renewal

ZIIHERA® (ZANIDATAMAB-HRII)

HCPCS: J9276

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Females of reproductive potential must have a negative pregnancy test prior to the first dose of therapy and will use an effective contraceptive method while receiving therapy and for four months following the last dose of therapy; **AND**
- Member has human epidermal growth factor receptor 2 (HER2)-positive (IHC3+) biliary tract cancer as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 2 MG)

1200 billable units every 14 days

LENGTH OF AUTHORIZATION

6 months for initial approval, 6 months for renewal

ZILRETTA® (TRIAMCINOLONE ACETONIDE ER)

HCPCS: J3304

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, etc.); **AND**
- Member has not received therapy with intra-articular hyaluronic acid derivative drugs within the previous 6 months of therapy; **AND**
- Member has not received therapy with intra-articular short-acting corticosteroid type drugs within the previous 3 months of therapy; **AND**
- Member has a diagnosis of osteoarthritis of the knee; **AND**
- Member has had a trial and failure to BOTH of the following conservative methods which have not resulted in functional improvement after at least three (3) months:
  - Non-Pharmacologic (i.e., physical, psychosocial, or mind-body approach [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
  - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- Member has failed to adequately respond to, or has a contraindication to, aspiration and injection of a short-acting intra-articular corticosteroid; **AND**
- Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

64 billable units one time only

LENGTH OF AUTHORIZATION

One dose per knee for initial approval, not eligible for renewal

ZOLEDRONIC ACID

HCPCS: J3489

CRITERIA FOR APPROVAL

Coverage is product specific and is provided under the following conditions:

Zometa®/zoledronic acid (branded)

- Member is at least 18 years of age; **AND**
- Member does not have hypocalcemia and will be adequately supplemented with calcium and vitamin D (Note: excludes when use is for hypercalcemia of malignancy); **AND**
- Member must have a CrCl ≥ 30 mL/min; **AND**
- Will not be used in combination with Reclast, other bisphosphonates, denosumab, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Member meets indication specific criteria below:

Hypercalcemia of malignancy

- Member has an albumin-corrected serum calcium level of ≥ 12 mg/dL.

Multiple Myeloma

- Member has a diagnosis of Multiple Myeloma.

Bone metastases from solid tumors

- Used in conjunction with standard antineoplastic therapy.

Reclast®

- Member is at least 18 years of age; **AND**
- Confirmation member is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Member must not have hypocalcemia; **AND**
- Member must have a CrCl ≥ 35 mL/min and no evidence of acute renal impairment; **AND**
- Will not be used in combination with Zometa, other bisphosphonates, denosumab, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Member meets indication specific criteria below:

Treatment and prevention of postmenopausal osteoporosis

- Member experienced severe intolerance, ineffective response, or has contraindications to oral bisphosphonate therapy; **OR**
- Member had a prior fragility fracture or is at especially high fracture risk.

Treatment to increase bone mass in men with osteoporosis

- Member experienced severe intolerance, ineffective response, or has contraindications to oral bisphosphonate therapy; **OR**
- Member had a prior fragility fracture or is at especially high fracture risk.

Treatment and prevention of glucocorticoid-induced osteoporosis

- Member experienced severe intolerance, ineffective response, or has contraindications to oral bisphosphonate therapy; **OR**
- Member had a prior fragility fracture or is at especially high fracture risk .

Treatment of Paget's disease of bone in men and women

- Serum alkaline phosphatase is two times or higher than the upper limit of the age-specific reference range; **OR**
- Member is symptomatic; **OR**
- Member is at risk for complications from their disease.

Note: For requests for non-FDA Approved indications, please submit documentation of medical necessity. These requests will be reviewed on a case-by-case basis and coverage may be provided if it is determined that:

- *the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, Micromedex, Lexi-Drug, etc…);* ***OR***
- *Submission is accompanied by published, peer-reviewed literature showing Level IIb or higher evidence for use of the product in the indication.*

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

5 billable units every 7 days

LENGTH OF AUTHORIZATION

12 months for initial approval, 12 months for renewal

ZOLGENSMA® (ONASEMNOGENE ABEPARVOVEC-XIOI)

HCPCS: J3399

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member must be less than 2 years of age; **AND**
- Member has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene; **AND**
- Member must have SMA phenotype 1 confirmed by one or more of the following:
  - Member must have 1-2 copies of the SMN2 gene; **OR**
  - Member has 3 or 4 copies of the SMN2 gene in the absence of the c.859G>C single base substitution modification in exon 7; **AND**
- Member must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA; **AND**
- Baseline liver function will be assessed prior to initiating therapy and will continue to be monitored for at least 3 months after therapy; **AND**
- Used concomitantly with systemic corticosteroids (see dosage/administration below); **AND**
- Member does not have advanced disease (complete limb paralysis, permanent ventilation support, etc.); **AND**
- Will not be used in combination with other agents for SMA (e.g., nusinersen, risdiplam, etc.).

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

1 billable unit (1 treatment of up to $5x10^{15}$ vector genomes)

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

ZUSDURI™ (MITOMYCIN)

HCPCS: J9282

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have a neurogenic bladder, active urinary retention or any other condition that would prohibit normal voiding of urine; **AND**
- Member does not have a perforation of the bladder or mucosal compromise until bladder integrity has been restored; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**
- Member is not a candidate for generically available mitomycin [J9280] instilled intravesically; **AND**
- Member has low-grade non-muscle invasive bladder cancer (NMIBC); **AND**
- Member has recurrent intermediate-risk disease defined as having one or two of the following:
  - Presence of multiple tumors
  - Solitary tumor > 3 cm
  - Early or frequent recurrence (≥ 1 occurrence of low-grade NMIBC within 1 year of the current diagnosis); **AND**
- Member has not received treatment with Bacillus Calmette-Guerin (BCG) or intravesical chemotherapy (except for a single-dose post-TURBT) for high-grade NMIBC.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

80 billable units every week for 6 weeks

LENGTH OF AUTHORIZATION

6 weeks for initial approval, not eligible for renewal

ZYNLONTA® (LONCASTUXIMAB TESIRINE-LPYL)

HCPCS: J9359

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Member has not received prior anti-CD19 therapy OR member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Member does not have active graft-versus-host disease; **AND**
- Member has not had an autologous stem cell transplant (ASCT) within 30 days or allogeneic stem cell transplant (AlloSCT) with 60 days, prior to start of therapy; **AND**
- Member does not have active CNS lymphoma (includes leptomeningeal disease); **AND**
- Member does not have a clinically significant active infection; **AND**
- Member does not have any clinically significant third space fluid accumulation (e.g., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath); **AND**
- Member has a diagnosis of large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma; **AND**
  - Member has received at least two prior lines of therapy; **AND**
  - Member has had no response or partial response OR has relapsed, progressive, or refractory disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 0.075 MG)

267 billable units every 21 days for cycles 1 and 2, then 134 billable units every 21 days for subsequent cycles

LENGTH OF AUTHORIZATION

6 month for initial approval, 6 months for renewal

ZYNTEGLO™ (BETIBEGLOGENE AUTOTEMCEL)

HCPCS: J3393

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 4 years of age; **AND**
- Provider has considered use of prophylaxis therapy for seizures prior to initiating myeloablative conditioning; **AND**
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Member does not have a history of hypersensitivity to dimethyl sulfoxide (DMSO); **AND**
- Member has not used prophylactic HIV anti-retroviral medication or hydroxyurea within 30 days prior to mobilization (or for the expected duration for elimination of those medications) and until all cycles of apheresis are completed (Note: if a member requires anti-retrovirals for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization and apheresis); **AND**
- Iron chelation therapy has been discontinued for at least 7 days prior to initiating myeloablative conditioning therapy and myelosuppressive iron chelators will be avoided for 6 months post-treatment; **AND**
- Member has not received other gene therapies (e.g., Casgevy [exagamglogene autotemcel], etc.)**; **AND**
- Member will receive periodic life-long monitoring for hematological malignancies; **AND**
- Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT; **AND**
- Member does not have a known and available human leukocyte antigen (HLA) matched family donor willing to participate in an allogeneic HSCT; **AND**
- Member has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
  - Member diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
  - Member has severe microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A (HbA) and increased HbA2 with or without increased amounts of hemoglobin F (HbF); **AND**
- Member has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) or with 8 or more transfusions of pRBCs per year in the 2 years preceding therapy; **AND**
- Member will be maintained at a Hb ≥ 11 g/dL for 30 days prior to mobilization and 30 days prior to myeloablative conditioning; **AND**
- Member does not have any of the following:

- Severely elevated iron in the heart (i.e., members with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI]); **OR**
- Advanced liver disease (i.e., persistent AST, ALT, or direct bilirubin value > 3 times the upper limit of normal (ULN), baseline prothrombin time or partial thromboplastin time > 1.5 times the ULN, MRI of the liver demonstrated cirrhosis, or liver biopsy demonstrated bridging fibrosis, active hepatitis, or cirrhosis); **OR**
- Members with an MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)

** Requests for subsequent use of betibeglogene after receipt of other gene therapies (e.g., exagamglogene, etc.) will be evaluated on a case-by-case basis.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 DOSE)

A single dose of Zynteglo containing a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

LENGTH OF AUTHORIZATION

One treatment course, not eligible for renewal

ZYNYZ® (RETIFANLIMAB-DLWR)

HCPCS: J9345

CRITERIA FOR APPROVAL

Coverage is provided under the following conditions:

- Member is at least 18 years of age; **AND**
- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified; **AND**
- Used as single agent therapy, unless otherwise specified; **AND**
- Member meets indication specific criteria below:

Squamous Cell Carcinoma of the Anal Canal (SCAC)

- Used in combination with carboplatin and paclitaxel for first-line treatment of inoperable locally recurrent or metastatic disease; **OR**
- Used for locally recurrent disease with progression on or intolerance to platinum-based chemotherapy; **OR**
- Used as subsequent therapy for metastatic disease.

Merkel Cell Carcinoma (MCC)

- Member has metastatic or recurrent locally advanced disease.

RENEWAL CRITERIA

- Member continues to meet the relevant criteria identified in the initial criteria; **AND**
- Member has an absence of unacceptable toxicity from the drug; **AND**
- Member is being continuously monitored for a beneficial response to therapy.

QUANTITY LIMITS (1 BILLABLE UNIT = 1 MG)

500 billable units every 21 days

LENGTH OF AUTHORIZATION

6 month for initial approval, 6 months for renewal