ARKANSAS MEDICAID

PHYSICIAN ADMINISTERED DRUG PROGRAM PRIOR AUTHORIZATION CRITERIA

This document is an informational listing of the medications requiring a Prior Authorization through the Arkansas Medicaid Physician Administered Drug Program, and a description of the associated criteria. Inclusion in this document does not guarantee market availability.

Revised 01/01/2026

Arkansas Medicaid Physician Administered Drug Criteria

Revised: January 1, 2026

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ABRAXANE AND GENERIC VERSIONS (PACLITAXEL PROTEIN-BOUND PARTICLES)

Updated: 04/21/2025

INDICATIONS

Abraxane is indicated for the treatment of:

- **Metastatic Breast Cancer**
- **Non-Small Cell Lung Cancer (NSCLS)**
- **Metastatic Pancreatic Adenocarcinoma**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.

Breast Cancer

- Treatment of metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or after relapse within 6 months of adjuvant chemotherapy. Prior therapy must have included an anthracycline unless clinically contraindicated.
- May be used in combination with atezolizumab (Tecentriq) for beneficiaries with unresectable locally advanced or metastatic disease.

Non-Small Cell Lung Cancer (NSCLC)

- Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) as first-line treatment in combination with carboplatin in beneficiaries who are not candidates for curative surgery or radiation therapy.
  - For beneficiaries with squamous NSCLC and PD-L1 expression < 50%, used in combination with carboplatin and pembrolizumab (Keytruda), based on the demonstrated survival benefit of this regimen over chemotherapy alone for beneficiaries with advanced, squamous NSCLC.

Pancreatic Adenocarcinoma

- Treatment of metastatic adenocarcinoma of the pancreas as first-line treatment in combination with gemcitabine.

RECOMMENDED OFF-LABEL USES

Non-Small Cell Lung Cancer (NSCLC)

- Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) as subsequent monotherapy treatment with or without previous immunotherapy (e.g., Opdivo, Keytruda, Tecentriq).

Triple-Negative Breast Cancer (TNBC)

- Treatment of recurrent unresectable (local or regional) or metastatic HR-negative and HER2-negative breast cancer as first-line therapy in combination with Keytruda (pembrolizumab) when PD-L1 ≥ 10.
- May be administered for HR-negative and HER2-negative breast cancer, as monotherapy therapy in beneficiaries with hypersensitivity reaction or intolerance to standard paclitaxel).

Adenocarcinoma of the Pancreas

- Treatment of locally advanced or metastatic pancreatic adenocarcinoma as first-line therapy in combination with gemcitabine.
- Used as second-line therapy after progression with fluoropyrimidine-based therapy.
- Neoadjuvant treatment in combination with gemcitabine for borderline resectable, non-metastatic disease.

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., neutrophil counts of < 1,500 cells/mm^3, sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions, myelosuppression, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9264 – Injection, paclitaxel protein-bound particles, 1 mg
- J9267 – Injection, paclitaxel, 1 mg

ACTEMRA (TOCILIZUMAB)

Updated: 01/23/2025

INDICATIONS

Actemra is indicated for treatment of:

- **Rheumatoid Arthritis**
- **Giant Cell Arteritis (GCA)**
- **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA)**
- **Systemic Juvenile Idiopathic Arthritis (SJIA)**
- **Cytokine Release Syndrome (CRS)**
- **Coronavirus Disease 2019 (COVID-19)**

CLINICAL CRITERIA

- The beneficiary must have been evaluated and screened for the presence of latent TB infection prior to initiating treatment
- The beneficiary does not have an active infection, including clinically important localized infections
- The drug must not be administered concurrently with live vaccines
- The beneficiary is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, or other biologic agent (e.g., apremilast [Otezla])

Rheumatoid Arthritis

- Adult beneficiaries must have moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs)
- The drug is prescribed by or in consultation with a rheumatologist
- The drug may be used alone or in combination with methotrexate

Juvenile Idiopathic Arthritis (JIA)

- Beneficiaries must be 2 years of age or older with active polyarticular juvenile idiopathic arthritis
- The drug is prescribed by or in consultation with a rheumatologist
- May be used alone or in combination with methotrexate

Cytokine Release Syndrome (CRS)

- Adults and pediatric beneficiaries must be 2 years of age or older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome
- Drug is prescribed by or in consultation with a rheumatologist

Giant Cell Arteritis

- The beneficiary has a diagnosis of giant cell arteritis
- The drug is prescribed by or in consultation with a rheumatologist

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

- Used for slowing the rate of decline in pulmonary function in adult beneficiaries with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Systemic Juvenile Idiopathic Arthritis (SJIA)

- The beneficiary is 2 years of age or older with active systemic juvenile idiopathic arthritis.

Coronavirus Disease 2019 (COVID-19)

- For treatment of hospitalized adult beneficiaries with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

APPROVAL DURATION

- Approval is for 6 months and may be renewed.
- **Note**: Actemra is **NOT** renewable for cytokine release syndrome

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., neutropenia, thrombocytopenia, hepatotoxicity, gastrointestinal perforation, severe hypersensitivity reactions, etc.)
- Beneficiary is receiving ongoing monitoring for presence of TB or other active infections
- **Rheumatoid arthritis (RA)**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline
- **Juvenile Idiopathic Arthritis (SJIA/PJIA)**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline
- **Cytokine Release Syndrome**
  - May not be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3262 – Injection, tocilizumab, 1 mg; 1 billable unit = 1 mg

ADAKVEO (CRIZANLIZUMAB-TMCA)

Updated: 02/15/2025

INDICATIONS

Adakveo is indicated to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric beneficiaries 16 years of age or older with sickle cell disease.

- **Sickle Cell Disease**

CLINICAL CRITERIA

- The beneficiary is 16 years of age or older
- The beneficiary has a diagnosis of sickle cell disease defined as any genotypes:
  - Homozygous hemoglobin S
  - Hemoglobin Sβ0-thalassemia
  - Hemoglobin Sβ+-thalassemia
  - Hemoglobin SC
- The beneficiary has a prior history of 2 or more sickle cell-related pain crises in the previous 12 months; **AND**
- The beneficiary has one of the following:
  - The beneficiary is currently receiving hydroxyurea therapy; **OR**
  - The beneficiary has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy
- Adakveo is prescribed by or in consultation with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
- Hb level ≥ 4 g/dL
- Adakveo is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced
- Documentation that the beneficiary was screened for tobacco use.
  - If the beneficiary smokes tobacco, the provider will submit a smoking cessation plan or documentation that the beneficiary received tobacco cessation intervention (either counseling or pharmacotherapy).

EXCLUSIONS

- The beneficiary is less than 16 years of age with sickle cell disease
- The beneficiary concurrently prescribed or taking Oxbryta (voxelotor)
- Myelofibrosis

APPROVAL DURATION

Initial approval is provided for 6 months and reauthorization will be for no more than 12 months

RENEWAL/REAUTHORIZATION

Adakveo (crizanlizumab-tmca) may be renewed when all of the following conditions are met:

- The beneficiary continues to meet initial approval guidelines and prescribing indications for sickle cell disease
- Absence of unacceptable toxicity from the drug (e.g. severe infusion-related reactions)
- The beneficiary has experienced a reduction in sickle cell-related vasoocclusive crises or a decrease in severity of sickle cell-related vasocculsive crises from pretreatment baseline while on Adakveo
- The beneficiary is not receiving concomitant Oxbryta (voxelotor) therapy
- The beneficiary must have at least one tobacco use screening during the 12-month period

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0791 – Injection, crizanlizumab-tmca, 5 mg; 1 billable unit = 20 mg

ADCETRIS (BRENTUXIMAB VEDOTIN)

Updated: 01/01/2026

INDICATIONS

Adcetris is indicated for treatment of beneficiaries with:

- **Classical Hodgkin Lymphoma (cHL)**
- **Non-Hodgkin Lymphoma**

CLINICAL CRITERIA

- The beneficiary is 2 years of age or older, unless otherwise specified.
- The drug must be prescribed by a hematologist or oncologist for:
  - Adult beneficiaries with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine.
  - Pediatric beneficiaries 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.
  - Adult beneficiaries with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
  - Adult beneficiaries with classical Hodgkin lymphoma (cHL) after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in beneficiaries who are not auto-HSCT candidates.
  - Adult beneficiaries with previously untreated systemic (i.e., not primary cutaneous) anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone.
  - Adult beneficiaries with beneficiaries with previously untreated systemic (i.e., not primary cutaneous) anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.
  - Adult beneficiaries with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.
  - In combination with lenalidomide and a rituximab product for adult beneficiaries with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or CAR T-cell therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

- Absence of unacceptable toxicity from the drug (e.g., progressive multifocal leukoencephalopathy, peripheral neuropathy, anaphylaxis and infusion reactions, hematologic toxicities [thrombocytopenia, neutropenia and anemia], serious infections, tumor lysis syndrome, increased toxicity in beneficiaries with severe renal [CrCl < 30 mL/min] and hepatic impairment [Child-Pugh B or C], hepatotoxicity, pulmonary toxicity, serious dermatologic reactions, gastrointestinal complications, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9042 - Injection, brentuximab vedotin, 1 mg; 1 billable unit = 1 mg

AFLIBERCEPT (EYLEA, EYLEA HD, EYDENZELT, PAVBLU)

Updated: 12/06/2024

INDICATIONS

Eylea is indicated for the treatment of beneficiaries with:

- **Neovascular (wet) age-related macular degeneration (AMD)**
- **Macular edema following retinal vein occlusion (RVO)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy (DR)**
- **Retinopathy of prematurity (ROP)**

Eylea HD is indicated for the treatment of beneficiaries with:

- **Neovascular (wet) age-related macular degeneration (nAMD)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy (DR)**
- **Macular edema following retinal vein occlusion (RVO)**

Eydenzelt is indicated for the treatment of beneficiaries with:

- **Neovascular (wet) age-related macular degeneration (AMD)**
- **Macular edema following retinal vein occlusion (RVO)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy (DR)**

Pavblu is indicated for the treatment of beneficiaries with:

- **Neovascular (wet) age-related macular degeneration (AMD)**
- **Macular edema following retinal vein occlusion (RVO)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy (DR)**

COMPENDIA RECOMMENDED INDICATIONS

- Vitreous hemorrhage

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- Treatment is prescribed by or in consultation with an ophthalmologist
- The beneficiary does not have active intraocular inflammation, ocular, or periocular infection
- The beneficiary has a diagnosis of one of the following **(refer to FDA approved indications)**:
    - Neovascular (wet) age-related macular degeneration (AMD)
    - Macular edema following retinal vein occlusion (RVO)
    - Diabetic macular edema (DME)
    - Diabetic retinopathy (DR)
    - Retinopathy of prematurity (ROP) **(currently FDA approved for Eylea only)**

COMPENDIA PRESCRIBING CONSIDERATIONS

Eylea use in vitreous hemorrhage is off-label per FDA prescribing indications. However, evidence from medical literature and prescribing guidelines indicates that intravitreal anti-VEGF agent use is safe and effective in the treatment of vitreous hemorrhage.

APPROVAL DURATION

Approval is for 6 months of treatment.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events, etc.)
- Beneficial response to therapy
- Continued administration is necessary for the maintenance treatment of the condition

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0178 – Injection, aflibercept, 1 mg; 1 billable unit = 1 mg (Eylea Only)
- J0177 – Injection, aflibercept hd, 1 mg; 1 billable unit = 1 mg (Eylea HD Only)
- Q5147 – Injection, aflibercept-ayyh, (Pavblu)

AFSTYLA (ANTIHEMOPHILIC FACTOR)

Updated: 02/12/2025

INDICATIONS

Afstyla is indicated in treatment of adults and children with hemophilia A (congenital Factor VIII deficiency) for:

- **On-demand treatment and control of bleeding episodes**
- **Routine prophylaxis to reduce the frequency of bleeding episodes**
- **Perioperative management of bleeding**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of congenital factor VIII deficiency
- The drug is used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes
  - Perioperative management
  - Routine prophylaxis
    - Used to prevent or reduce the frequency of bleeding episodes
    - The beneficiary must have severe hemophilia A (factor VIII level of <1%); **OR**
    - The beneficiary has at least two documented episodes of spontaneous bleeding into joints

EXCLUSIONS

- Afstyla is not indicated for the treatment of von Willebrand disease.

APPROVAL DURATION

- Approval is for 6 months for On-demand treatment and control of bleeding episodes AND for Routine prophylaxis.
- **Note**: Lengthy approval periods (e.g., 6 months) for use in perioperative management do not meet medical necessity. Therefore, approval duration when Afstyla is used for perioperative management is limited to 1 month.

RENEWAL/REAUTHORIZATION

May be renewed.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7210 - Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 IU

ALTUVIIIO (ANTIHEMOPHILIC FACTOR [RECOMBINANT], FC-VWF-XTEN FUSION PROTEIN-EHTL)

Updated: 11/19/2025

INDICATIONS

Altuviiio, a recombinant DNA-derived Factor VIII concentrate, is indicated for use in **hemophilia A** in adults and children for:

- **Routine prophylaxis** to reduce the frequency of bleeding episodes
- **On-demand treatment and control** of bleeding episodes
- **Perioperative management** of bleeding

CLINICAL CRITERIA

- The beneficiary has a documented diagnosis of severe hemophilia A (less than 1% endogenous Factor VIII).
- The beneficiary has documentation that Altuviiio is being prescribed for one of the following:
  - Treatment of bleeding episodes
  - Prevention of bleeding in surgical interventions or invasive procedures (surgical prophylaxis)
  - Prevention of bleeding episodes/routine prophylaxis
- If the beneficiary has had a past trial and failure with other Factor VIII agents (e.g., Adynovate, Eloctate, Jivi, etc.), the requesting provider has submitted documentation that the failure was not due to a decreased response (clinical signs or symptoms) to the product.
- The prescriber attests that the beneficiary does not have clinical manifestations suggesting the presence of Factor VIII inhibitors.
- Altuviiio is prescribed by or in consultation with a hematologist.
- The beneficiary is not concurrently be using other factor VIII products or Hemlibra (emicizumab-kxwh).

LIMITATIONS OF USE

Altuviiio is not indicated for the treatment of von Willebrand disease.

APPROVAL DURATION

Approval is for six months and may be renewed, except for surgical prophylaxis.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has documentation that they have experienced a positive therapeutic response from Altuviiio, as defined by at least **one** of the following:
  - Reduced frequency of bleeds
  - Reduced severity of bleeds
- **Note**: Objective markers to consider for continuation or renewal of therapy include initial and ongoing response to therapy, such as assessing ABR (annualized bleeding rate), joint health status,

frequency and severity of bleeds (including spontaneous, traumatic, and target joints), and breakthrough bleeds.
  - Additionally, monitoring beneficiaries with hemophilia (chronic maintenance use) and their allocation to prophylaxis or on-demand (frequency of acute use) treatment may be necessary for consideration of renewal/reauthorization.
- **Note**: No reauthorization is allowed for surgical prophylaxis renewal requests.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7214 – Injection, Factor VIII/von Willebrand factor complex, recombinant (Altuviiio), per Factor VIII IU

AMONDYS 45 (CASIMERSEN)

Updated: 02/12/2025

INDICATIONS

Amondys 45 is FDA approved for:

- **Duchenne Muscular Dystrophy (DMD)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of Duchenne muscular dystrophy (DMD) by or in consultation with a neurologist with expertise in the diagnosis of DMD
- Submission of medical records confirming the mutation of the DMD gene is amenable to exon 45 skipping
- The beneficiary has been on stable dose of oral corticosteroids, unless contraindicated or intolerance, for at least 3 months
- The beneficiary is not concurrently treated with other DMD antisense oligonucleotides (e.g., golodirsen [Vyondys 53], viltolarsen [Viltepso], or eteplirsen [Exondys 51]).
- Baseline documentation of the following:
  - Pulmonary Function Test (PFT)
  - End-tidal capnography (ETCo2)
  - Timed 30-foot walk
  - Time to go up 4 stairs
  - Brooke scale for upper extremity
  - Vignos scale for lower extremity

APPROVAL DURATION

Authorization is limited to 6 months at a time.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., renal toxicity/proteinuria, etc.)
- Follow-up functional test results must show stabilization or improvement of beneficiary function compared to baseline measures.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1426 – Injection, casimersen, 10 mg; 1 billable unit = 10 mg

AMVUTTRA (VUTRISIRAN) INJECTION FOR SUBCUTANEOUS USE

Updated: 11/13/2025

INDICATIONS

Amvuttra is indicated for the treatment of:

- **Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults**
- **Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults** to reduce cardiovascular mortality, cardiovascular hospitalizations, and urgent heart failure visits

CLINICAL CRITERIA

Polyneuropathy of transthyretin-mediated amyloidosis

- The beneficiary has a diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP), as confirmed by ONE of the following:
  - Confirmation of a TTR mutation verified by genotyping; **OR**
  - Tissue biopsy confirming the presence of amyloid deposits
- The beneficiary does not have any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- The prescriber must submit the following documentation:
  - Baseline modified Neuropathy Impairment Score +7 (mNIS+7)
  - Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
  - Previous therapies tried
  - Current labs including LFTs and BMP
- Amvuttra is prescribed by or in consultation with a neurologist, geneticist, or physician specializing in the treatment of amyloidosis.

Cardiomyopathy of transthyretin-mediated amyloidosis

- The beneficiary has a diagnosis of wild-type or hereditary transthyretin amyloid cardiomyopathy.
- Documentation is provided that the diagnosis has been confirmed with TWO of the following:
  - Echocardiogram; **OR**
  - Tissue biopsy confirming the presence of transthyretin amyloid deposits; **OR**
  - Cardiovascular magnetic resonance imaging:
    - If consistent with cardiac amyloidosis, the following tests must be performed to document the presence or absence of monoclonal protein:
      - Serum kappa/lambda free light chain ratio analysis
      - Serum protein immunofixation
      - Urine protein immunofixation
    - If monoclonal protein is not found, bone tracer cardiac scintigraphy (pyrophosphate scan) must be performed. The presence of grade 2 or 3 is highly specific for ATTR cardiac disease; tissue biopsy is **not** needed, but genetic testing **is** needed to confirm TTR variant.

- The beneficiary must have New York Heart Association Class (NYHA) I, II, or III heart failure with symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema).
- The beneficiary must have left ventricular wall (interventricular septum or left ventricular posterior wall) thickness ≥ 12 mm.
- The beneficiary should not be approved or continue the medication if they meet one of the following:
  - Impaired renal function (eGFR < 15 mL/min/1.73m^2)
  - Baseline NT-proBNP < 300 pg/mL or ≥ 8,500 pg/mL
- The prescriber must submit the following documentation:
  - Baseline 6-minute walk distance (6MWD)
  - Current labs including baseline eGFR and NT-proBNP level (≥ 300 pg/mL)
  - Baseline echocardiogram with NYHA classification and documentation of tests results confirming the diagnosis
  - Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score.
  - Medical necessity over Attruby and Vyndaqel/Vyndamax
- Amvuttra is prescribed by or in consultation with a neurologist, geneticist, or physician specializing in the treatment of amyloidosis.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of positive clinical response to therapy, as demonstrated by clinically significant improvement or stabilization in clinical signs and symptoms of the disease (e.g., motor strength, ambulation, neurological symptom burden, quality of life, activities of daily living).

RECOMMENDED DOSING

The recommended dosage of Amvuttra is 25 mg administered by subcutaneous injection once every 3 months.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0225 – Injection, vutrisiran, 1 mg (Amvuttra)

ARRANON (NELARABINE)

Updated: 02/12/2025

INDICATIONS

Arranon is indicated for treatment of:

- **T-cell Acute Lymphoblastic Leukemia (T-ALL)**
- **T-cell Lymphoblastic Lymphoma (T-LBL)**

CLINICAL CRITERIA

T-ALL & T-LBL

- The beneficiary must be age 1 year of age or older
- The beneficiary must have clinically documented T-cell acute lymphoblastic leukemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL)
- The drug is indicated for beneficiaries whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens.
- The drug may also be used as first-line therapy along with chemotherapy
- All applicable laboratory or test results and drug usage must be supported by documentation
- Female beneficiaries of childbearing age must have pregnancy status verified prior to therapy
- Must be prescribed by an oncologist or hematologist

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is not a candidate for bone marrow transplant
- The beneficiary has disease that is stable, not progressing
- The beneficiary tolerates treatment without any unacceptable toxicity or hypersensitivity to the drug
- The beneficiary may require close monitoring of neurologic adverse reactions. Severe neurologic events (e.g., mental status changes, somnolence, convulsions, peripheral neuropathy ranging from numbness and paresthesia to motor weakness and paralysis) may indicate toxicity, and treatment must be discontinued.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9261 – Injection, nelarabine, 50 mg

ANTI-VASCULAR ENDOTHELIAL GROWTH FACTOR: AVASTIN (BEVACIZUMAB)

Updated: 08/27/2025

OFF-LABEL INDICATIONS

Bevacizumab (Avastin) use in ophthalmology is off label, meaning it is not FDA approved for ocular use. However, evidence from medical literature and prescribing guidelines recommend use of Avastin because of the drug's long history of safety and efficacy.

CLINICAL CRITERIA

- The provider is an ophthalmologist; **AND**
- The beneficiary has a documented diagnosis of one of the following conditions:
  - Neovascular (Wet) Age-Related Macular Degeneration
  - Diabetic Macular Edema (DME)
  - Macular Edema following Retinal Vein Occlusion (RVO)
  - Diabetic Retinopathy (DR) with or without Diabetic Macular Edema (DME)
  - Myopic Choroidal Neovascularization (mCNV)
  - Neovascular Glaucoma
  - Vitreous Hemorrhage
  - Retinal Neovascularization

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of progress showing current medical necessity of an approved indication
- Documentation of medication effectiveness and beneficiary response

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7999 - Injection, bevacizumab for ophthalmic use, 1.25 mg; 1 billable unit = 0.25 mg

APRETUDE (CABOTEGRAVIR)

Updated: 06/13/2024

INDICATIONS

Apretude is indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Beneficiaries must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

CLINICAL CRITERIA

- The beneficiary must weigh ≥ 35 kg.
- Apretude is prescribed for pre-exposure prophylaxis (PrEP) of HIV.
- The beneficiary must have a negative HIV-1 test immediately prior to initiating Apretude
- The beneficiary is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease).
- The provider agrees to confirm that the beneficiary is HIV-1 infection status negative before each injection.
- The provider agrees to transition the beneficiary to a complete HIV-1 treatment regimen if the beneficiary acquires HIV-1 infection during treatment with Apretude.
- The provider attests that medication adherence counseling was performed.

ADMINISTRATION

- For gluteal intramuscular injection only.
- Prior to initiating Apretude, an oral lead-in dosing may be used for approximately 1 month with the recommended dosage to assess the tolerability of Apretude.
- Initiate Apretude with a single 600 mg (3mL) injection given 1 month apart for 2 consecutive months on the last day of an oral lead-in, if used, or within 3 days with continued injections every 2 months thereafter.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- A negative HIV-1 test
- Confirmation by the provider that the beneficiary will be tested for HIV-1 infection before each subsequent injection.

LIMITATIONS OF USE

Apretude is unproven and not medically necessary for the treatment of HIV-1.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0739 - Kit containing one 600 mg/3 mL single-dose vial of cabotegravir extended-release suspension

ASPARAGINE SPECIFIC ENZYMES: ASPARLAS, ERWINAZE, RYLAZE

Updated: 10/23/2024

INDICATIONS

Erwinaze and **Rylaze** are indicated for treatment of:

- **Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL) (approved indications)** or extranodal natural killer/T-cell lymphoma (based on NCCN guidelines)
  - The beneficiary is 1 month of age or older
  - The drug is prescribing by or in consultation with an oncologist or hematologist
  - The drug is prescribed as a component of a multi-agent chemotherapeutic regimen
  - The beneficiary has developed hypersensitivity to E. coli-derived asparaginase

Asparlas is indicated for treatment of:

- **Acute Lymphoblastic Leukemia (ALL)**
  - The beneficiary is at least 1 month to 21 years of age
  - Asparlas is prescribed by or in consultation with an oncologist or hematologist
  - Asparlas is used as a component of a multi-agent chemotherapy regimen
- **Lymphoblastic Lymphoma**

CONTRAINDICATIONS

Contraindications to Erwinaze and Rylaze

- History of serious thrombosis with prior L-asparaginase therapy
- History of serious pancreatitis related to prior L-asparaginase treatment
- History of serious hemorrhagic events with prior L-asparaginase treatment

Contraindications to Asparlas

- History of serious hypersensitivity reactions to pegylated L-asparaginase
- History of serious thrombosis during L-asparaginase therapy
- History of serious pancreatitis related to previous L-asparaginase treatment
- History of serious hemorrhagic events during previous L-asparaginase treatment
- Severe hepatic impairment

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Stabilization of disease or absence of progression of disease
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions [including anaphylaxis], serious thrombotic events, hemorrhage, severe hepatotoxicity, pancreatitis, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9118 – Injection, calaspargase pegol-mknl, 10 units, 1 billable unit = 10 units
- J9019 – Injection, asparaginase (Erwinaze), 1,000 IU. 1 billable unit = 1,000 IU
- J9021 – Injection, asparaginase (Rylaze), 10 mg/0/5 mL. 1 billable unit = 10 mg

BENDAMUSTINE (BENDEKA; TREANDA; VIVIMUSTA)

Updated: 05/16/2024

INDICATIONS

First-line treatment of chronic lymphocytic leukemia (CLL) as well as indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed on treatment that includes rituximab.

- **Chronic Lymphocytic Leukemia (CLL)**
- **Indolent B-cell non-Hodgkin Lymphoma (NHL)**

The National Comprehensive Cancer Network (NCCN) provides additional recommendations with a category 2A level of evidence for the use of bendamustine. These recommendations include the use alone or in combination for previously treated multiple myeloma for relapse or progressive disease; as well as second-line, subsequent, or palliative therapy for classic Hodgkin lymphoma. NCCN also recommends bendamustine alone or in combination for primary, previously treated, progressive, or relapsed Waldenstrom's macroglobulinemia. Bendamustine is recommended by NCCN for other types of non-Hodgkin lymphoma (NHL).

- **B-Cell lymphomas:**
  - **AIDS-related B-cell lymphoma**
  - **Diffuse large B-cell lymphoma**
  - **Follicular lymphoma**
  - **Gastric MALT lymphoma**
  - **Nodal marginal zone lymphoma**
  - **Nongastric MALT lymphoma**
  - **Post-transplant lymphoproliferative disorders**
  - **Splenic marginal zone lymphoma**
- **T-Cell lymphomas:**
  - **Adult T-cell leukemia/lymphoma**
  - **Peripheral T-cell lymphomas**
  - **Breast Implant-associated Anaplastic Large Cell Lymphoma (ALCL)**
  - **Hepatosplenic T-cell lymphoma**
- **Small Cell Lung Cancer (SCLC)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of one of the following:
  - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); **OR**
  - Relapsed or refractory classical Hodgkin lymphoma; **OR**
  - Non-Hodgkin lymphoma (NHL); **OR**
  - Relapsed or progressive multiple myeloma; **OR**
  - Relapsed or refractory systemic light chain amyloidosis; **OR**
  - Waldenstrom's macroglobulinemia; **OR**
  - Cold agglutinin disease

Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (CLL/SLL)

- Used as first-line therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with rituximab or ofatumumab (Arzerra) or obinutuzumab (Gazyva) in beneficiaries without del(17p)/TP53 mutations
- Used as subsequent therapy, after prior Bruton Tyrosine Kinase inhibitor- and venetoclax-based regimens; **AND**
  - Used in combination with rituximab for disease without del(17p)/TP53 mutatinos in beneficiaries < 65 years of age without significant comorbidities.

Non-Hodgkin Lymphoma (NHL)

- Approval is provided for B-Cell Lymphomas when:
  - Used as first-line therapy with rituximab in beneficiaries < 65 years of age; **OR**
  - Used as first-line, second-line or subsequent therapy in combination with rituximab or obinutuzumab (Gazyva) for:
    - Follicular lymphoma; **OR**
  - Used as a second-line or subsequent therapy in combination with rituximab or as a single agent for:
    - Mantle cell lymphoma
    - Diffuse large B-cell lymphoma
    - AIDS-related B-cell lymphoma
    - Post-transplant lymphoproliferative disorder; **OR**
  - Used as a second-line or subsequent therapy in combination with rituximab or obinutuzumab for:
    - Non-gastric MALT lymphoma
    - Gastric MALT lymphoma
    - Splenic marginal zone lymphoma
    - Nodal marginal zone lymphoma

Classical Hodgkin Lymphoma (CHL)

- Used as a single agent; **OR**
- Used in combination with gemcitabine (Gemzar) and vinorelbine (Navelbine); **OR**
- Used in combination with brentuximab vedotin (Adcetris)

Diffuse Large B-cell Lymphoma

- Used in combination with polatuzumab vedotin-piiq (Polivy) and a rituximab product

Small Cell Lung Cancer (SCLC)

- Used as a second-line or subsequent therapy for relapsed or refractory disease

EXCLUSIONS

Requests for bendamustine agents may not be approved for the following:

- Treatment of metastatic breast cancer
- Treatment of small cell lung cancer (SCLC)

APPROVAL DURATION

- For **CLL**:
  - Approval is for up to 6 cycles (28-day cycles)
- For **non-Hodgkin lymphoma**:
  - Approval up to 8 cycles (21-day cycles)

RENEWAL/REAUTHORIZATION

Authorizations cannot be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9034 – Injection, bendamustine HCl (bendeka), 1 mg: 1 billable unit = 1 mg
- J9033 – Injection, bendamustine HCl (Treanda), 1 mg: 1 billable unit = 1 mg
- J9056 – Injection, bendamustine hydrochloride (vivimusta), 1 mg

BAVENCIO (AVELUMAB)

Updated: 07/15/2024

INDICATIONS

Bavencio is indicated for treatment of:

- **Merkel cell carcinoma (MCC)**
- **Urothelial carcinoma**
- **Renal cell carcinoma**

CLINICAL CRITERIA

Merkel cell carcinoma (MCC)

- Adults and pediatric beneficiaries 12 years of age and older with metastatic MCC.

Bladder cancer/urothelial carcinoma

- Maintenance treatment of beneficiaries with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy.
- Beneficiaries with locally advanced or metastatic UC who have:
  - Disease progression during or following platinum-containing chemotherapy.
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Renal cell carcinoma

- First-line treatment, in combination with axitinib (Inlyta), for beneficiaries with advanced RCC

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug, (e.g., severe infusion reactions, hepatotoxicity, immune-mediated adverse reactions [pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, myocarditis, pancreatitis, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barre syndrome, systemic inflammatory response, etc.], major adverse cardiovascular events, etc.)

BILLING/CODING INFORMATION

- J9023 – Injection, avelumab, 10 mg; 1 billable unit = 10 mg

BCG LIVE, TICE

Updated: 02/15/2025

INDICATIONS

BCG Live intravesical is indicated for treatment of:

- **Bladder cancer**

CLINICAL CRITERIA

- The beneficiary has diagnosis of carcinoma in situ of the urinary bladder
- **Note**: Use may cause tuberculin sensitivity. Since this is a valuable aid in the diagnosis of tuberculosis, it is advisable to determine the tuberculin reactivity by PPD skin testing before treatment.

EXCLUSIONS

- Beneficiaries with active tuberculosis
- Beneficiaries who are immunosuppressed
- Beneficiaries with congenital or acquired immune deficiencies

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has a standard treatment schedule consisting of one intravesical instillation per week for 6 weeks. This schedule may be repeated once if tumor remission has not been achieved and if warranted by clinical circumstances.
- The beneficiary does **not** have acute, localized irritative toxicities of BCG Live.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9030 - Bcg live intravesical instillation, 1 mg

BELEODAQ (BELINOSTAT)

Updated: 02/12/2025

INDICATIONS

Beleodaq is indicated for treatment of:

- **Relapsed or refractory peripheral T-cell lymphoma (PTCL)**

CLINICAL CRITERIA

Peripheral T-cell lymphoma (PTCL)

- The beneficiary is at least 18 years of age
- The disease is relapsed or refractory prior to treatment

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has a positive response with stabilization of disease
- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicity, severe infections, hepatoxicity, severe gastrointestinal toxicity, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9032 – Injection, belinostat, 10 mg; 1 billable unit = 10 mg

BENLYSTA (BELIMUMAB)

Updated: 01/23/2025

INDICATIONS

Benlysta is indicated for treatment of:

- **Systemic lupus erythematosus (SLE)**
- **Lupus nephritis**

CLINICAL CRITERIA

Systemic lupus erythematosus (SLE)

- The beneficiary is 5 years of age or older with active systemic lupus erythematosus (SLE) and is receiving standard therapy.

Lupus nephritis

- The beneficiary is 5 years of age or older.
- The beneficiary has active disease and is receiving standard therapy.

Warnings:

- Serious/fatal infections have occurred in beneficiaries receiving immunosuppressive agents, including Benlysta.
  - Use with caution in beneficiaries with severe or chronic infections.
  - Beneficiaries must not receive a live vaccine within 30 days before starting or concurrently with Benlysta.
  - Provider must evaluate beneficiaries with new-onset or deteriorating neurological signs and symptoms for progressive multifocal leukoencephalopathy (PML)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation from the provider of disease stability or improvement.
- Absence of unacceptable toxicity from the drug (e.g., depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy [PML], malignancy, severe hypersensitivity reaction, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0490 – Injection, belimumab, 10 mg; 1 billable unit = 10 mg

BESPONSA (INOTUZUMAB OZOGAMICIN)

Updated: 02/12/2025

INDICATIONS

Besponsa is indicated for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric beneficiaries 1 year of age and older.

- **Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)**

CLINICAL CRITERIA

- The drug is prescribed by an oncologist.
- The beneficiary is 1 year of age or older.
- The beneficiary has confirmed relapse or refractory disease.
  - The beneficiary is Philadelphia chromosome (Ph)-negative; **OR**
  - The beneficiary is Philadelphia chromosome (Ph)-positive and refractory to prior tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, nilotinib, bosutinib, etc.)

	Day 1	Day 8	Day 15
Dosing regimen for Cycle 1			
All beneficiaries			
Dose	0.8 mg/m^2	0.5 mg/m^2	0.5 mg/m^2
Cycle length	21 days*		
Dosing regimen for subsequent cycles depending on response to treatment			
Beneficiaries who have achieved a CR or CRi			
Dose	0.5 mg/m^2	0.5 mg/m^2	0.5 mg/m^2
Cycle length	28 days		
Beneficiaries who have not achieved a CR or CRi			
Dose	0.8 mg/m^2	0.5 mg/m^2	0.5 mg/m^2
Cycle length	28 days		

Note: *For beneficiaries who achieve a CR or a CRi or to allow for recovery from toxicity, the cycle length may be extended up to 28 days (i.e., 7-day treatment-free interval starting on day 21).

APPROVAL DURATION

Approval is for 6 months (for up to a maximum of 6 cycles)

RENEWAL/REAUTHORIZATION

Cannot be renewed.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9229 – Injection, inotuzumab ozogamicin, 0.1 mg; 1 billable unit = 0.1 mg.

BEVACIZUMAB (AVASTIN, ALYMSYS, MVASI, VEGZELMA, ZIRABEV)

Updated: 02/25/2025

INDICATIONS

Avastin, Alymsys, Mvasi, Vegzelma, and Zirabev are indicated for treatment of:

- **Colorectal cancer**
- **Non-squamous non-small cell lung cancer**
- **Recurrent glioblastoma in adults**
- **Cervical cancer**
- **Renal cell carcinoma**
- **Epithelial ovarian, fallopian tube, or primary peritoneal cancer**
- **Hepatocellular carcinoma (HCC)**

CLINICAL CRITERIA

- **Colorectal cancer**
  - Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; **OR**
  - Used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based regimen as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab-containing regimen.
  - **Limitations of use**: Bevacizumab-products are not indicated for adjuvant treatment of colon cancer.
  - **Note**: See **Compendia Indications** below for guidelines for use of Bevacizumab in combination with LONSURF (trifluridine and tipiracil) for metastatic colorectal cancer.
- **Non-squamous non-small cell lung cancer**
  - Unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer (NSCLC), in combination with carboplatin and paclitaxel for first-line treatment
- **Recurrent glioblastoma in adults**
  - Glioblastoma, as a single agent or in combination with lomustine, for adult beneficiaries with progressive disease following prior therapy.
- **Cervical cancer**
  - Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or with paclitaxel and topotecan
- **Renal cell carcinoma**
  - Metastatic renal cell carcinoma (RCC) in combination with interferon alfa
- **Epithelial ovarian, Fallopian Tube, or Primary Peritoneal cancer**
  - Used in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for stage III or IV disease following initial surgical resection.

- Used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent, or progressive disease in beneficiaries who have received no more than 2 prior chemotherapy regimens.
- Used in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by a Bevacizumab-product as a single agent, for platinum-sensitive recurrent or progressive disease.
- **Note**: See **Epithelial ovarian/fallopian tube/primary peritoneal cancer** under **Compendia off-label use**s (below) for additional therapy regimens

- **Hepatocellular Carcinoma (HCC)**
  - Used in combination with atezolizumab (Tecentriq) for the treatment of beneficiaries with unresectable or metastatic HCC who have not received prior systemic therapy.

COMPENDIA RECOMMENDED INDICATIONS AND OFF-LABEL USES

- **Breast cancer**
  - The beneficiary must have recurrent or metastatic disease
  - The beneficiary has a high tumor burden or rapidly progressive disease
  - The drug must be used in combination with paclitaxel
  - The beneficiary must be human epidermal growth factor receptor 2 (HER2)-negative
    - Disease is hormone receptor-negative
    - Disease is hormone receptor-positive and refractory to endocrine therapy
    - Beneficiary has symptomatic visceral disease or visceral crisis
- **Colorectal cancer**
  - LONSURF is a combination of trifluridine and tipiracil indicated for the treatment of metastatic colorectal cancer as a single agent or in combination with **bevacizumab** in adult beneficiaries who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, if RAS wild-type, an anti-EGFR therapy.
- **Central nervous system cancer (including radiation-induced brain necrosis)**
  - The drug is used for symptom management related to **radiation necrosis**, poorly controlled vasogenic edema or mass effect as single agent.
  - The beneficiary has a diagnosis of one of the following other CNS cancers:
    - Grade III/IV astrocytoma
    - Primary CNS lymphoma
    - Meningiomas
    - Brain, spine, or leptomeningeal metastases
    - Medulloblastoma
    - Recurrent glioblastoma or anaplastic gliomas
    - Recurrent intracranial or spinal ependymoma
  - The drug is used as a single agent OR in combination with one of the following: irinotecan, carmustine, lomustine, or temozolomide in beneficiaries with recurrent glioblasomas or anaplastic gliomas
  - The drug can be used as single agent therapy for progressive disease in beneficiaries with a diagnosis of recurrent intracranial and spinal ependymoma but who do not have subependymomas.

- The drug can be used for treatment of unresectable recurrent or progressive disease when radiation therapy is not an option in beneficiaries with a diagnosis of menigiomas

- **Soft tissue sarcoma**
  - The drug is used as a single agent for angiosarcoma
  - The drug is used in combination with temozolomide for solitary fibrous tumor or hemangiopericytoma
- **Endometrial carcinoma**
  - The drug is used as a single agent therapy for disease that has progressed on prior cytotoxic therapy.
  - The drug is used in combination with carboplatin and paclitaxel for advanced or recurrent disease.
- **Malignant pleural mesothelioma**
  - The beneficiary has unresectable or metastatic disease.
  - The drug must be used in combination with pemetrexed and either cisplatin or carboplatin followed by single agent maintenance therapy
- **Progressive vestibular schwannoma**
- **AIDS-related Kaposi sarcoma**
  - The beneficiary has relapsed or refractory disease
  - The beneficiary has advanced cutaneous, oral, visceral, or nodal disease
  - The drug is used as subsequent therapy in combination with antiretroviral therapy after failure of two lines of systemic therapy.
- **Renal cell carcinoma**
  - Advanced papillary RCC, including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC, in combination with erlotinib (Tarceva)
- **Epithelial ovarian, fallopian tube, or primary peritoneal cancer**
  - The beneficiary has recurrent cancer
  - The drug may be used as single agent or in combination with carboplatin and liposomal doxorubincin

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., gastrointestinal perforation, surgical or wound healing complications, hemorrhage, arterial and venous thromboembolic events, uncontrolled hypertension, posterior reversible encephalopathy syndrome, nephrotic syndrome, severe infusion reactions, ovarian failure, congestive heart failure, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9035 – Injection, bevacizumab, 10 mg; 1 billable unit = 10 mg
- Q5107 – Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
- Q5118 – Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg
- Q5126 – Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg; 1 billable unit = 10 mg
- Q5129 – Injection, bevacizumab-adcd, biosimilar, (vegzelma), 10 mg; 1 billable unit = 10 mg

BLENREP (BELANTAMAB MAFODOTIN-BLMF)

Updated: 02/12/2025

INDICATIONS

Blenrep is indicated for treatment of:

- **Relapsed or refractory multiple myeloma**

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age or older.
- The beneficiary has relapsed or refractory disease.
- The beneficiary has disease progression on at least four prior anti-myeloma treatment regimens that must have included **one or more** agents from **each** of the following categories:
  - A proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib, etc.)
  - An immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide, etc.)
  - An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab-irfc, etc.)
- Therapy will be used in combination with preservative-free lubricant eye drops.
- The beneficiary does not have current corneal epithelial disease (**Note**: Mild punctuate keratopathy is excluded)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., ophthalmic toxicity, severe infusion related reactions, thrombocytopenia, etc.)

BILLING/CODING INFORMATION

- J9037 – Injection, belantamab mafodontin-blmf, 0.5 mg; 1 billable unit – 0.5 mg

BLINCYTO (BLINATUMOMAB)

Updated: 09/09/2024

INDICATIONS

Blincyto is indicated for treatment of:

- **CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL**) in first or second complete remission with Minimal Residual Disease (MRD) ≥ 0.1%.
- **Relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL)**
- **CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL)** in consolidation phase of multiphase chemotherapy.
- **CD19-positive B-cell ALL** in beneficiaries who are **MRD negative** after initial or first-line treatment.

CLINICAL CRITERIA

B-cell precursor acute lymphoblastic leukemia

- Beneficiary is at least 1 month old
- For use as single agent therapy
  - Beneficiary has Relapsed or Refractory disease; **OR**
  - For use in beneficiaries with Minimal Residual Disease (MRD) positive as consolidation therapy following a complete response/remission to induction therapy; **OR**
  - For use in beneficiaries with MRD negative after initial, or first-line therapy.

APPROVAL DURATION

Relapsed or refractory B-cell precursor acute lymphocytic leukemia (ALL)

- For the treatment of relapsed or refractory B-cell ALL, the labeling for Blincyto recommends hospitalization for the first 9 days of the first cycle and the first 2 days of the second cycle.
- A treatment course consists of up to 2 cycles of Blincyto for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.
- A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days).
- A single cycle of treatment of Blincyto continued therapy consists of 28 days of continuous intravenous infusion followed by a 56-day treatment-free interval (total 84 days).

MRD-positive B-cell precursor acute lymphocytic leukemia (ALL)

- For the treatment of MRD-positive B-cell precursor ALL, the labeling for Blincyto recommends hospitalization for the first 3 days of the first cycle and the first 2 days of the second cycle.
- A treatment course consists of 1 cycle of Blincyto for induction followed by up to 3 additional cycles for consolidation.
- A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., cytokine release syndrome, neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome, neutropenia or febrile neutropenia, elevation of LFTs, leukoencephalopathy, etc.)
- Treatment response or stabilization of disease, as indicated by CBC, bone marrow cytogenic analysis, quantitative polymerase chain reaction (qPCR), or fluorescent in situ hybridization (FISH); **AND**
  - The beneficiary has not exceeded a total of 4 cycles of continued therapy or 9 total cycles of Blincyto for the treatment of relapsed or refractory disease; **OR**
  - Continued therapy for use in the treatment of MRD positive acute lymphoblastic leukemia may not be renewed.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9039 – Injection, blinatumomab 1 microgram; 1 billable unit = 1 microgram

BOTOX (ONABOTULINUMTOXINA)

Updated: 11/15/2024

INDICATIONS

Botox is indicated for treatment of:

- Treatment of **overactive bladder (OAB)** with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Treatment of **urinary incontinence due to detrusor overactivity** associated with a neurologic condition (e.g., spinal cord injury [SCI], multiple sclerosis [MS]) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- Treatment of **neurogenic detrusor overactivity (NDO)** in pediatric beneficiaries 5 years of age or older who have an inadequate response to or are intolerant of anticholinergic medication.
- **Prophylaxis of headaches** in adult beneficiaries with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
- Treatment of **spasticity** in beneficiaries 2 years of age and older.
- Treatment of **cervical dystonia** in adult beneficiaries, to reduce the severity of abnormal head position and neck pain.
- Treatment of **severe axillary hyperhidrosis** that is inadequately managed by topical agents in adult beneficiaries.
- Treatment of **blepharospasm** associated with dystonia in beneficiaries 12 years of age or older.
- Treatment of **strabismus** in beneficiaries 12 years of age or older.

OFF-LABEL USES

- Abdominal wall **hernia** procedure
- Chronic pain associated with **hallux valgus**.

CLINICAL CRITERIA

- The beneficiary has not experienced unacceptable toxicity from the drug (e.g., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, swallowing/breathing difficulties, etc.)
- The beneficiary anticipates/expects improvement, or disease response is evidenced by improvement in symptoms

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0585 – Injection, onabotulinumtoxinA, 1 unit; 1 billable unit = 1 unit

BREYANZI (LISOCABTAGENE MARALEUCEL)

Updated: 12/08/2025

INDICATIONS

Large B-cell lymphoma (LBCL)

- The beneficiary is at least 18 years of age.
- The healthcare facility/provider has enrolled in the Breyanzi REMS.
- The beneficiary has a documented diagnosis of large B-cell lymphoma including any of the following:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma)
  - High grade B-cell lymphoma (HGBCL)
  - Primary mediastinal large B-cell lymphoma (PMBCL)
  - Follicular lymphoma (FL) grade 3B
- The beneficiary has been treated with first line therapy containing an anthracycline and rituximab (or another CD20-targeted agent).
- The beneficiary has one of the following:
  - Relapsed or refractory disease after two or more lines of systemic therapy.
  - Disease refractory to first-line chemoimmunotherapy (primary refractory) or relapse within 12 months of first-line chemoimmunotherapy.
  - Disease refractory to first-line chemoimmunotherapy (primary refractory) or relapse after first-line chemoimmunotherapy, and the beneficiary is ineligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age.
- The beneficiary does **NOT** have any of the following:
  - Primary central nervous system (CNS) lymphoma.
  - Prior CAR T-cell or other genetically-modified T-cell therapy.
- The beneficiary has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Mantle Cell Lymphoma (MCL)

- The beneficiary is at least 18 years of age.
- The healthcare facility/provider has enrolled in the Breyanzi REMS.
- The beneficiary has a documented diagnosis of relapsed or refractory MCL.
- The beneficiary has been treated with 2 or more prior lines of systemic therapy, including the following:
  - An alkylating agent
  - A CD20-targeted drug (e.g., rituximab)
  - A covalent Bruton tyrosine kinase inhibitor (BTKi) (e.g., ibrutinib, acalabrutinib, or zanubrutinib).
- The beneficiary does **NOT** have any of the following:
  - Primary central nervous system (CNS) lymphoma.
  - Prior CAR T-cell or other genetically-modified T-cell therapy.

- The beneficiary has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Follicular Lymphoma (FL)

- The beneficiary is at least 18 years of age.
- The healthcare facility/provider has enrolled in the Breyanzi REMS.
- The beneficiary has a documented diagnosis of relapsed or refractory FL (grade 3B).
- The beneficiary has been treated with 2 or more prior lines of systemic therapy, including an alkylating agent and CD20-targeted drug (e.g., rituximab).
- The beneficiary does **NOT** have any of the following:
  - Primary central nervous system (CNS) lymphoma.
  - Prior CAR T-cell or other genetically-modified T-cell therapy.
- The beneficiary has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV). and human immunodeficiency virus (HIV).

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

- The beneficiary is at least 18 years of age.
- The healthcare facility/provider has enrolled in the Breyanzi REMS.
- The beneficiary has a documented diagnosis of relapsed or refractory CLL or SLL.
- The beneficiary has been treated with 2 or more prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor (venetoclax).
- The beneficiary does **NOT** have any of the following:
  - Primary central nervous system (CNS) lymphoma.
  - Prior gene therapy.
- The beneficiary has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Marginal zone lymphoma

- The beneficiary is at least 18 years of age.
- The beneficiary has relapsed or refractory marginal zone lymphoma (MZL) and has received at least 2 prior lines of systemic therapy.

EXCLUSIONS

Breyanzi is **NOT** indicated for the treatment of beneficiaries with:

- Primary central nervous system lymphoma
- Previous treatment course with the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy
- ECOG performance status score greater than or equal to 3
- Active hepatitis B, active hepatitis C or any active uncontrolled infection
- Active graft versus host disease
- Active inflammatory disorder

APPROVAL DURATION

Approval will be provided for one treatment course (1 dose of Breyanzi) and may not be renewed.

RENEWAL/REAUTHORIZATION

Breyanzi will not be reauthorized for continued therapy.

RECOMMENDED DOSING

- Breyanzi (lisocabtagene maraleucel) is a cell suspension for infusion.
- A single dose of Breyanzi consists of 1:1 CAR-positive viable T cells of CD8 and CD4 components, with each component supplied separately in one to four single-dose 5 mL vials. Each mL contains ≥ 1.5×10^6 to 70×10^6 CAR-positive viable T cells.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Q2054 – Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 car-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

BRINEURA (CERLIPONASE ALFA)

Updated: 10/28/2024

INDICATIONS

Brineura is indicated for treatment of:

- **Neuronal ceroid lipofuscinosis type 2 (CLN2); tripeptidyl peptidase 1 (TPP1)**

CLINICAL CRITERIA

- Pediatric beneficiary of any age
- The beneficiary must have a definitive diagnosis of CLN2 confirmed by deficiency of the lysosomal enzyme tripeptidyl peptidase-1 (TPP1) or the detection of pathogenic mutations in each allele of the TPP1 gene (aka CLN2 gene)
- Presence of mild-to-moderate disease documented by a two-domain score of 3-6 on motor and language domains of the Hamburg CLN2 Clinical Rating Scale, with a score of at least 1 in each of these two domains.
- The beneficiary is ambulatory.
- Beneficiaries with a history of bradycardia, conduction disorder, or with structural heart disease must have electrocardiogram (ECG) monitoring performed during the infusion.

EXCLUSIONS

- The beneficiary must not have ventriculoperitoneal shunts.
- The beneficiary must not have acute intraventricular access device-related complications (e.g. leakage, device failure, or device-related infection)

APPROVAL DURATION

Authorization will be for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug or complications from the device (e.g. intraventricular access device leakage or infection, severe hypersensitivity reaction, severe hypotension, etc.)
- 12-lead ECG evaluation performed within the last 6 months (those with cardiac abnormalities require ECG during each infusion)
- Positive response to therapy compared to pretreatment baseline with stability/lack of decline in motor function/milestones on the Motor domain of the Hamburg CLN2 Clinical Rating Scale (decline is defined as having an unreversed [sustained] 2-category decline or an unreversed score of 0)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Unclassified biologics
- C9014 – Injection, cerliponase alfa, 1 mg: 1 billable unit = 1 mg

BRIUMVI (UBLITUXIMAB-XIIY)

Updated: 09/09/2025

INDICATIONS

- **Relapsing multiple sclerosis (RMS), including:**
  - **Clinically isolated syndrome (CIS)**
  - **Relapsing-remitting disease (RRMS)**
  - **Active secondary progressive disease (SPMS)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of relapsing multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease.
- The beneficiary is at least 18 years of age.
- Clinical notes document both baseline number of relapses per year and expanded disability status scale (EDSS) score.
- The beneficiary is able to ambulate without aid or rest for at least 100 meters (corresponding to EDSS score of 0–5.5).
- When initiating therapy, the beneficiary has experienced one of the following:
  - At least two relapses within the previous two years; **OR**
  - One relapse within the previous year; **OR**
  - At least one T1 gadolinium-enhancing lesion on MRI within the previous year.
- The beneficiary has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment AND the beneficiary does not have active disease (i.e., positive HBsAg and anti-HBV tests).
- Briumvi is prescribed by or in consultation with a neurologist.
- The drug must be used as single agent therapy.

ADDITIONAL PRESCRIBING CONSIDERATIONS

Requests for Briumvi may be approved when the following conditions are met:

- Documentation has been provided that the beneficiary has been on Briumvi (ublituximab); **OR**
- Documentation has been provided that the beneficiary has had a trial of and inadequate response (including clinical relapse, new or enlarged lesions on MRI or confirmed disability progression) or intolerance to fumaric acid derivative; **OR**
- Documentation has been provided that the beneficiary has high disease activity despite treatment with fingolimod (Gilenya, Tascenso ODT), defined as the following:
  - At least one relapse in the previous year while on therapy; **AND**
  - At least 9 T2 hyperintense lesions in cranial MRI; **OR**
    - At least one Gadolinium-enhancing lesion.

EXCLUSIONS

- Briumvi is not prescribed or administered concurrently with other disease-modifying therapies for multiple sclerosis (MS), with the exception of dalfampridine, which may be used in combination with Briumvi.
- Briumvi is not prescribed to treat non-active secondary progressive multiple sclerosis.
- Active hepatitis B or other active infection at initiation of therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of positive clinical response or stable disease based on at least one of the following:
  - The beneficiary has not had an increase in the number of relapses per year compared to baseline; **OR**
  - The beneficiary has had 1 or fewer new MRI-detected lesions; **OR**
  - The beneficiary has not had an increase in expanded disability status scale (EDSS) score from baseline; **OR**
  - Medical justification supports that beneficiary is responding positively to therapy.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy, hypogammaglobulinemia, etc.).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2329 - Injection, ublituximab-xiiy, 1 mg (Briumvi)

BYOOVIZ (RANIBIZUMAB-NUNA)

Updated: 04/08/2025

INDICATIONS

Byooviz is indicated for treatment of:

- **Neovascular (wet) age-related macular degeneration (AMD)**
- **Macular edema following retinal vein occlusion (RVO)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy**
- **Myopic choroidal neovascularization (mCNV)**

CLINICAL CRITERIA

- The beneficiary is free from ocular and peri-ocular infections
- The beneficiary has a definitive diagnosis of one of the following:
  - Neovascular (wet) age-related macular degeneration (AMD)
  - Diabetic macular edema (DME)
  - Diabetic retinopathy
  - Macular edema following retinal vein occlusion (RVO)
  - Myopic choroidal neovascularization (mCNV)

OFF LABEL USES

- **Vitreous Hemorrhage**
- **Retinopathy of Prematurity (ROP)**
- Byooviz use in vitreous hemorrhage and retinopathy of prematurity are off label, per FDA prescribing indications. However, evidence from medical literature and prescribing guidelines indicate that intravitreal anti-VEGF agent use is safe and effective in their treatment.

APPROVAL DURATION

- Approval for myopic choroidal neovascularization (mCNV) will be provided for 3 months and may be renewed
- Approval for all other indications will be provided for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has experienced a beneficial response to therapy.
- Continued administration is necessary for the maintenance treatment of the condition.
- For myopic choroidal neovascularization ONLY
  - Continued administration is necessary due to disease activity (e.g., decrease in vision, visual symptoms [e.g., metamorphopsia], or the presence of intra-/sub-retinal fluid or active leakage)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Unclassified biologics

CABENUVA (CABOTEGRAVIR/RILPIVIRINE)

Updated: 10/16/2025

INDICATIONS

Cabenuva is indicated as a complete regimen for the treatment of:

- **HIV-1 infection** in adults and adolescents 12 years of age or older who weigh at least 35 kg.

CLINICAL CRITERIA

- The beneficiary has viremia (i.e., elevated HIV-1 RNA level [viral load]).
- The beneficiary is at high risk of disease progression (e.g., CD4 count < 200 cells per microliter, history of acquired immunodeficiency syndrome [AIDS]-defining complications).
- The beneficiary is 12 years of age or older.
- The beneficiary's weight is ≥ 35 kg.
- The beneficiary is currently virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months.
- The beneficiary is unable to achieve or maintain virologic suppression while on oral antiretroviral therapy (ART), despite intensive medication adherence support.
- The beneficiary has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine.
- Cabenuva is being prescribed by or in consultation with an infectious disease or HIV specialist.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation is provided that the beneficiary has not experienced a virologic failure while on Cabenuva. Failure is defined as two consecutive plasma HIV-1 RNA levels (viral load) ≥ 200 copies per mL.

DOSAGE AND ADMINISTRATION

- **Recommended monthly dosing schedule**: Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or oral lead-in and continue with injections of Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter.
- **Recommended every-2-month dosing schedule**: Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or oral lead-in for 2 consecutive months and continue with injections of Cabenuva every 2 months thereafter.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0741 - Injection, cabotegravir and rilpivirine, 2 mg/3 mg

CARVYKTI (CILTACABTAGENE AUTOLEUCE)

Updated: 05/29/2025

INDICATIONS

Carvykti (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult beneficiaries with relapsed or refractory multiple myeloma.

CLINICAL CRITERIA

- The beneficiary is 18 years old and older.
- The beneficiary has a confirmed diagnosis of relapsed or refractory multiple myeloma that has progressed on 4 or more lines of therapy.
- The beneficiary has triple class refractory disease, defined as refractory to:
  - An immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide)
  - A protease inhibitor (e.g., bortezomib, carfilzomib [Kyprolis], ixazomib [Ninlaro]); **AND**
  - An anti-CD38 antibody (e.g., daratumumab [Darzalex], isatuximab [Sarclisa]).
- The beneficiary has not previously been treated with chimeric antigen receptor (CAR-T) therapy (e.g., Abecma, Breyanzi, Kymriah, Tecartus, Yescarta).

EXCLUSIONS

- The beneficiary has had prior treatment with any form of CAR-T therapy, including therapies in clinical trial settings.
- The beneficiary does not have measurable disease, defined as any of the following:
  - Serum monoclonal paraprotein (M-protein) level ≥ 1.0 g/dL or urine Mprotein level ≥ 200 mg/24 hours; **OR**
  - Light chain multiple myeloma without measurable disease in the serum or the urine: Serum immunoglobulin free light chain 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio.

APPROVAL DURATION

- Authorization for Carvykti is limited to a one-time infusion.
- Beneficiaries who have had prior treatment with any form of CAR-T therapy, including therapies in clinical trial settings, will not be approved for additional CAR-T therapy.

RENEWAL/REAUTHORIZATION

Authorizations may not be renewed. Carvykti is limited to a one-time infusion.

DOSING

Approval of up to 1 x 10^8 CAR-T cells administered intravenous as a single dose.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Q2056 - Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR positive T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose

CEREZYME (IMIGLUCERASE)

Updated: 02/14/2025

INDICATIONS

Cerezyme is indicated for treatment of:

- **Gaucher disease**

CLINICAL CRITERIA

- The beneficiary is 2 years of age or older.
- The beneficiary has a documented diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions:
  - Anemia
  - Thrombocytopenia
  - Bone disease
  - Hepatomegaly
  - Splenomegaly

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response from drug usage, as indicated by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine or femoral neck BMD, no bone crises or bone fractures, etc.)
  - Improvement in platelet counts.
- Absence of unacceptable toxicity from the drug, including hypersensitivity reactions.

BILLING/CODING INFORMATION

- J1786 – Injection, imiglucerase, 10 units; 1 billable unit = 10 units

CIMZIA (CERTOLIZUMAB PEGOL)

Updated: 02/14/2025

INDICATIONS

Cimzia is indicated for:

- **Crohn's disease**
- **Rheumatoid arthritis (RA)**
- **Polyarticular juvenile idiopathic arthritis (pJIA)**
- **Psoriatic arthritis**
- **Ankylosing spondylitis**
- **Axial spondyloarthritis**
- **Plaque psoriasis**

CLINICAL CRITERIA

- The beneficiary has been evaluated and screened for the presence of latent TB infection prior to initiating treatment
- The beneficiary has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
- The beneficiary does not have an active infection, including clinically important localized infections
- The drug must not be administered concurrently with live vaccines
- The beneficiary is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast [Otezla])
- The beneficiary is 18 years of age or older unless otherwise indicated.
- The requesting provider has assessed baseline disease severity utilizing an objective measure/tool

Crohn's Disease

- The drug is used to reduce signs and symptoms of Crohn's disease and maintain clinical response in adult beneficiaries with moderately to severely active disease who have had an inadequate response to conventional therapy

Rheumatoid Arthritis (RA)

- The beneficiary has documented moderate to severe active disease.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

- The beneficiary is 2 years of age and older.

Psoriatic Arthritis

- The beneficiary has documented moderate to severe active disease

Ankylosing Spondylitis

- The beneficiary has documented active disease.

Axial Spondyloarthritis

- The beneficiary has active non-radiographic disease with objective signs of inflammation

Plaque Psoriasis

- The beneficiary has moderate-to-severe disease and is a candidate for systemic therapy or phototherapy.

COMPENDIA RECOMMENDATIONS

Acute Anterior Uveitis

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as indicated by improvement in signs and symptoms compared to baseline.
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infection, cardiotoxicity or heart failure, lupus-like syndrome, demyelinating disease, cytopenia, development of malignancies, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0717 – Injection, certolizumab pegol, 1 mg; 1 billable unit = 1mg

CINVANTI (APREPITANT)

Updated: 02/14/2025

INDICATIONS

Cinvanti is indicated for prevention of:

- Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen.
- Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single dose regiment.
- Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a 3-day regimen.

CLINICAL CRITERIA

Prevention of chemotherapy induced nausea and vomiting

- The beneficiary is 18 years of age or older.
- The beneficiary is receiving highly or moderately emetogenic chemotherapy (see HEC/MEC list below)
- The drug must be used in combination with a 5-HT3 antagonist (e.g., ondansetron, granisetron, palonosetron, etc.)
- The drug must be used in combination with a corticosteroid (e.g., dexamethasone)
- Use of Cinvanti with other drugs that are CYP3A4 substrates is contraindicated

Highly / Moderately Emetogenic Chemotherapy (HEC/MEC)	
Highly Emetogenic Chemotherapy (HEC)	**Moderately Emetogenic Chemotherapy (MEC)**
Carboplatin	Aldesleukin
Carmustine	Amifostine
Cisplatin	Arsenic Trioxide
Cyclophosphamide	Azacitidine
Dacarbazine	Bendamustine
Doxorubicin	Busulfan
Epirubicin	Clofarabine
Ifosfamide	Cytarabine
Mechlorethamine	Dactinomycin
Streptozocin	Daunorubicin
	Dinutuximab
	Idarubicin
	Interferon alfa
	Irinotecan
	Melphalan
	Methotrexate
	Oxaliplatin

Highly / Moderately Emetogenic Chemotherapy (HEC/MEC)	
	Temozolomide
	Trabectedin
The following regimens can be considered HEC	
FOLFOX	

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of drug effectiveness in preventing chemotherapy-induced nausea and vomiting

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0185 – Injection, aprepitant, 1 mg

CONTINUOUS GLUCOSE MONITORING SYSTEM (E.G., DEXCOM)

Updated: 03/04/2025

INDICATIONS

Continuous Glucose Monitoring Systems, such as DexCom is approved and indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin for the purpose of improving diabetes management.

CLINICAL CRITERIA

- The beneficiary has a paid claim for a CGM transmitter or sensor in the last 60 days; **OR**
- The beneficiary has a diagnosis of gestational diabetes (Group O24) in the past 365 days of the beneficiary's history that is submitted on the incoming pharmacy claim or documented on the request; **OR**
- The beneficiary has diagnosis of diabetes (ICD-10 E10 or E11) in the past 365 days of the beneficiary's history that is submitted on the incoming pharmacy claim or documented on the request; **AND**
  - The beneficiary is currently using insulin, substantiated by a paid pharmacy claim in the last 124 days; **OR**
    - The prescriber attests that the beneficiary is currently utilizing insulin; **AND**
  - The beneficiary's current insulin regimen is documented on the request; **OR**
  - The beneficiary has a diagnosis of level 3 hypoglycemia (ICD-10 E16.1) in the past 365 days of the beneficiary's history that is submitted on the incoming pharmacy claim or documented on the request; **OR**
  - The beneficiary has lab history in the last 365 days for blood glucose level of ≤ 54 mg/dL (level 2 hypoglycemia); **OR**
  - The beneficiary has a paid claim for a glucagon agent in the last 365 days; **OR**
- The beneficiary has a diagnosis of glycogen storage disease type 1a (ICD-10 E74.01) in the past 365 days of the beneficiary's history that is submitted on the incoming pharmacy claim or documented on the request; **OR**
- The beneficiary has a paid claim for a patch-type insulin pump in the last 365 days

APPROVAL DURATION

Authorization will be for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Success of a personal continuous glucose monitoring device is highly dependent on compliance. Documentation for renewal must include an assessment by beneficiary's healthcare provider or diabetes nurse educator indicating that the beneficiary is compliant with self-monitoring as described above.

BILLING/CODING INFORMATION

Applicable Procedure Codes

Procedure Code[1]	Modifier (M1)[2]	Description
K0553		• Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service • Class II system
K0553	KF	• Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service • Class III system
K0554		• Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system • Class II system
K0554	KF	• Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system • Class III system
[1] These procedure codes replace the procedure codes currently being used to file a claim for CGM systems and supplies. [2] The **M1 modifier KF** must be used when billing for Class III CGM systems and supplies.		

COSELA (TRILACICLIB)

Updated: 10/27/2025

INDICATIONS

Cosela is indicated for treatment of:

- **Chemotherapy induced myelosuppression**

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC)
  - **Note**: Extensive stage-small-cell lung cancer is defined as tumors with distant metastasis or exceeding an area that can be treated within a radiation field
- The beneficiary is undergoing myelosuppressive chemotherapy with one of the following:
  - A platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
  - A topotecan-containing regimen.
- The drug is prescribed by or in consultation with an oncologist.
- The drug is not used except within 4 hours prior to chemotherapy administration.

ADDITIONAL RECOMMENDATIONS

The National Comprehensive Cancer Network (NCCN) Small Cell Lung Cancer guidelines (Version 2.2026) have addressed trilaciclib (Cosela).

- Trilaciclib or G-CSF may be used as prophylactic options to decrease the incidence of chemotherapy-induced myelosuppression when administering platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (ES-SCLC).

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of clinical benefit including positive response to therapy
- Absence of unacceptable toxicity from the drug (e.g., severe injection reactions including phlebitis and thrombophlebitis, acute drug hypersensitivity reactions, interstitial lung disease/pneumonitis, etc.)

DOSAGE/ADMINISTRATION

The recommended dose of Cosela is 240 mg/m^2 per dose. Administer as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.

BILLING/CODING INFORMATION

Applicable Procedure Codes

J1448 – Injection, Trilaciclib, 1 mg; 1 billable unit = 1 mg

CRYSVITA (BUROSUMAB-TWZA)

Updated: 11/18/2025

INDICATIONS

Crysvita is indicated for treatment of:

- **X-linked hypophosphatemia (XLH)** in adult and pediatric beneficiaries 6 months of age and older.
- **FGF23-related hypophosphatemia** in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric beneficiaries 2 years of age and older.

CLINICAL CRITERIA

- Must be prescribed by or in consultation with a residency trained nephrologist or endocrinologist
- The beneficiary has **not** received oral phosphate or active vitamin D analogs within 1 week prior to the start of therapy
- The beneficiary must be diagnosed with either:
  - X-linked hypophosphatemia (XLH); **OR**
  - FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)
- The 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 (PHEX-gene) mutations
  - Clinical, radiographic, and laboratory findings that support the diagnosis (e.g., evidence of Rickets, evidence of skeletal demineralization, low phosphate and high alkaline phosphatase activity for age)
- Baseline fasting serum phosphorus level with current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range
- The beneficiary does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of < 30 mL/min
- Adult beneficiaries must have had an inadequate response from oral phosphate and active vitamin D analogs

APPROVAL DURATION

Approval is for 6 months and may be renewed every 6 months thereafter

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, hyperphosphatemia or nephrocalcinosis, severe injection site reactions, etc.)

- Current serum phosphorus level is not above the upper limit of the laboratory normal reference range
- Disease response, as indicated by increased serum phosphorus levels, a reduction in serum total alkaline phosphatase activity, improvement in symptoms (e.g., skeletal pain, linear growth, etc.), or improvement in radiographic imaging of Rickets/osteomalacia
- Pediatric beneficiaries must be re-evaluated at adulthood or upon closure of bony epiphyses (whichever occurs first) in order to determine whether continued therapy is necessary (e.g., discontinuation of burosumab in order to reassess whether treatment with oral phosphate and active vitamin D analogs provide an adequate response)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0584 - Injection, burosumab-twza 1 mg; 1 billable unit = 1 mg

CYRAMZA (RAMUCIRUMAB)

Updated: 02/14/2025

INDICATIONS

Cyramza is indicated for treatment of:

- **Gastric, esophageal and gastro-esophageal junction adenocarcinoma**
- **Metastatic non-small cell lung cancer**
- **Metastatic colorectal cancer**
- **Hepatocellular carcinoma**

CLINICAL CRITERIA

- Used as a single agent or in combination with paclitaxe, for treatment of advanced or metastatic **gastric or gastro-esophageal junction adenocarcinoma** with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy.
- Used in combination with erlotinib for first-line treatment of metastatic **non-small cell lung cancer** with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.
- Used in combination with docetaxel for treatment of metastatic **non-small cell lung cancer** with disease progression on or after platinum-based chemotherapy. Beneficiaries with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza.
- Used in combination with FOLFIRI for the treatment of metastatic **colorectal cancer** with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
- Used as a single agent for the treatment of **hepatocellular carcinoma** in beneficiaries who have an alpha fetoprotein of ≥ 400 ng/mL and who have been treated with sorafenib.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with disease stabilization or decrease in size or spread of tumor.
- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, arterial thrombotic events, uncontrolled hypertension, infusion-related reactions, severe proteinuria (> 3 g/24 hours), gastrointestinal perforation, wound healing complications, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9308 – Injection, ramucirumab, 5 mg; 1 billable unit = 5 mg

DACOGEN (DECITABINE)

Updated: 03/04/2025

INDICATIONS

Dacogen is FDA-indicated for:

- **Myelodysplastic syndrome (MDS)**

ADDITIONAL APPROVED INDICATIONS

- **Acute myeloid leukemia (AML)**

COMPENDIA RECOMMENDED INDICATIONS

- Acute myeloid leukemia (AML)
- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Myelofibrosis (MF)
- Myelodysplastic/myeloproliferative (MDS/MPN) overlap syndrome ‡ (Includes use for chronic myelomonocytic leukemia type 1 or 2 [CMML-1 or 2], atypical chronic myeloid leukemia [aCML] BCR-ABL negative, MDS/MPN unclassified, and MDS/MPN with ring sideroblasts and thrombocytosis [MDS/MPN-RS-T])

CLINICAL CRITERIA

EXCLUSION

- Hypersensitivity to decitabine

CAUTIONS

- Use with caution in the elderly and in beneficiaries with hepatic/renal impairment.
- Male beneficiaries should not father a child during treatment and for two months post-treatment

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of benefit from treatment
- Absence of unacceptable toxicity from the drug

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0894 – Injection, decitabine, 1 mg: 1 billable unit = 1 mg
- J0893 – Injection, decitabine (sun pharma) not therapeutically equivalent to J0894, 1 mg; 1 billable unit = 1 mg

DANYELZA (NAXITAMAB-GQGK)

Updated: 03/04/2025

INDICATIONS

Danyelza is indicated for treatment of:

- **High-risk neuroblastoma**

CLINICAL CRITERIA

- The beneficiary is at least 1 year of age
- For children 1 to 18 years of age, Danyelza is prescribed by or in consultation with a pediatric oncologist
- The beneficiary has relapsed or refractory disease in the bone or bone marrow
- The beneficiary had at least a partial or minor response or stable disease to at least one prior systemic therapy
- The beneficiary does not have uncontrolled hypertension
- The drug is used in combination with granulocyte-macrophage colony-stimulating factor (e.g., Leukine [sargramostim])

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., serious infusion-related reactions, severe neurotoxicity, [including neuropathic pain, peripheral neuropathy, transverse myelitis, reversible posterior leukoencephalopathy syndrome, neurological disorders of the eye, and prolonged urinary retention], severe hypertension, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9348 – Injection, naxitamab-gqgk, 1 mg: 1 billable unit = 1 mg

DARZALEX (DARATUMUMAB)

Updated: 11/08/2025

INDICATIONS

Darzalex is indicated for treatment of:

- **Multiple myeloma (newly diagnosed and relapsed/refractory)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- The drug is prescribed by or in consultation with an oncologist or hemotologist

Multiple Myeloma

- Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in newly diagnosed beneficiaries who are ineligible for autologous stem cell transplant and in beneficiaries with relapsed or refractory multiple myeloma who have received at least one prior therapy
- Treatment of multiple myeloma in combination with bortezomib, melphalan, and prednisone in newly diagnosed beneficiaries who are ineligible for autologous stem cell transplant
- Treatment of multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed beneficiaries who are eligible for autologous stem cell transplant
- Treatment of multiple myeloma in combination with bortezomib and dexamethasone in beneficiaries who have received at least one prior therapy
- Treatment of multiple myeloma in combination with carfilzomib and dexamethasone in beneficiaries with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- Treatment of multiple myeloma in combination with pomalidomide and dexamethasone in beneficiaries who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor
- Treatment of multiple myeloma as monotherapy in beneficiaries who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or in beneficiaries who are double-refractory to a PI and an immunomodulatory agent

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Stabilization of disease or absence of progression of disease
- Absence of unacceptable toxicity from the drug (e.g., infusion reactions, neutropenia, thrombocytopenia, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9145 - Injection, daratumumab, 10 mg; 1 billable unit = 10 mg

DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)

Updated: 11/08/2025

INDICATIONS

Darzalex Faspro is indicated for treatment of:

- **Multiple myeloma** (in adult beneficiaries)
- **Light chain amyloidosis**

CLINICAL CRITERIA

Multiple myeloma

- Treatment of multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed beneficiaries who are eligible for autologous stem cell transplant
- Treatment of multiple myeloma in combination with bortezomib, melphalan and prednisone in newly diagnosed beneficiaries who are ineligible for autologous stem cell transplant
- Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in newly diagnosed beneficiaries who are ineligible for autologous stem cell transplant and in beneficiaries with relapsed or refractory multiple myeloma who have received at least one prior therapy
- Treatment of multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed beneficiaries who are eligible for autologous stem cell transplant
- Treatment of multiple myeloma in combination with bortezomib and dexamethasone in beneficiaries who have received at least one prior therapy
- Treatment of multiple myeloma in combination with pomalidomide and dexamethasone in beneficiaries who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- Treatment of multiple myeloma in combination with carfilzomib and dexamethasone in beneficiaries with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- Treatment of multiple myeloma as monotherapy in beneficiaries who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or in beneficiaries who are double-refractory to a PI and an immunomodulatory agent
- Treatment of high-risk smoldering multiple myeloma (SMM) as monotherapy

Light Chain (AL) Amyloidosis

- Light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone in newly diagnosed beneficiaries

EXCLUSIONS

- The drug will not be used in combination with other anti-CD38 therapies (e.g., daratumumab [Darzalex], isatuximab [Sarclisa], etc.)
- The drug is not indicated and is not recommended for the treatment of beneficiaries with light chain amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease and decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9144 - Injection, daratumumab, 10 mg and hyaluronidase-fihj; 1 billable unit=10 mg

DATROWAY (DATOPOTAMAB DERUXTECAN-DLNK)

Updated: 06/26/2025

INDICATIONS

Datroway is indicated for the treatment of:

- **Non-small cell lung cancer (NSCLC)**
- **Breast cancer**

CLINICAL CRITERIA

- Datroway is prescribed by or in consultation with an oncologist.

Non-small cell lung cancer

- Adult beneficiaries with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

Breast cancer

- Unresectable or metastatic hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+ or IHC 2+/ISH–) breast cancer in adults who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

DOSAGE AND ADMINISTRATION

Dose does not exceed 6 mg/kg (up to a maximum of 540 mg for beneficiaries ≥ 90 kg), administered as an intravenous infusion not more frequently than once every 3 weeks until disease progression or unacceptable toxicity.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease response with treatment and no evidence of disease progression while on therapy.
- Absence of unacceptable toxicity from Datroway

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Unclassified biologics
- J9999 – Not otherwise classified, antineoplastic drugs

DENOSUMAB (PROLIA/XGEVA), DENOSUMAB-BMWO (STOBOCLO/OSENVELT)

Updated: 09/24/2025

INDICATIONS

Prolia (denosumab)

- Prolia/Xgeva/Stoboclo are RANK ligand (RANKL) inhibitors indicated for:
  - Treatment of postmenopausal women with osteoporosis who are at high risk for fracture
  - Treatment to increase bone mass in men with osteoporosis who are at high risk for fracture
  - Treatment of glucocorticoid-induced osteoporosis in men and women who are at high risk for fracture
  - Treatment to increase bone mass in men who are at high risk for fracture and are receiving androgen deprivation therapy for non-metastatic prostate cancer.
  - Treatment to increase bone mass in women who are at high risk for fracture and are receiving adjuvant aromatase inhibitor therapy for breast cancer.

Stoboclo (denosumab-bmwo)

- The biosimilar to Prolia (denosumab) is FDA-approved for the same indications as Prolia.

Xgeva (denosumab)

- Prevention of skeletal-related events in beneficiaries with multiple myeloma and in beneficiaries with bone metastasis from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Osenvelt (denosumab-bmwo)

- The biosimilar to Xgeva (denosumab) is FDA-approved for the same indications as Xgeva.

CLINICAL CRITERIA

PROLIA (DENOSUMAB)/STOBOCLO (DENOSUMAB-BMWO)

- **Warnings and precautions**
  - Same active ingredient: Beneficiaries receiving Prolia should not receive Xgeva.
  - While receiving Prolia, the beneficiary should be taking calcium and vitamin, D unless contraindicated.
- The beneficiary is at least 18 years of age.
- The beneficiary must not have hypocalcemia.
- The beneficiary must be at a high risk for fracture** (see table below)
- **Osteoporosis in men and women**
  - Women only: The beneficiary must be postmenopausal
  - Both men and women: The beneficiary has a documented diagnosis of osteoporosis indicated by one or more of the following:

        - Bone mineral density scan (BMD) via bone density scan (DXA) T-score ≤ -2.5 at the conventional skeletal sites including the total hip, femoral neck, lumbar spine (posterior-anterior, not lateral), or radius
        - History of fragility fracture (other than skull, facial bone, finger, and toes) as an adult
        - Bone mineral density (BMD) T-score of -1.0 to -2.5 at the femoral neck or lumbar spine and a 10-year probability of hip fracture > 3% or a 10-year probability of a major osteoporosis-related fracture > 20% based on the U.S. adapted World Health Organization (WHO) algorithm
    - Documented contraindication, intolerance, treatment failure, or ineffective response* to both oral bisphosphonates and intravenous (IV) bisphosphonates (e.g., alendronate, risedronate, ibandronate, or zoledronic acid).
- **Osteoporosis treatment and prevention in prostate cancer beneficiaries**
    - The beneficiary must have one of the following:
        - Bone mineral density (BMD) T-score ≤ -1.0 at the conventional skeletal sites including the total hip, femoral neck, lumbar spine (posterior-anterior, not lateral) or radius (or the beneficiary meets the diagnostic criteria for osteoporosis)
        - The beneficiary must be receiving androgen deprivation therapy for nonmetastatic prostate cancer
- **Osteoporosis treatment and prevention in breast cancer beneficiaries**
    - The beneficiary must be receiving adjuvant aromatase inhibitor therapy for breast cancer

XGEVA (DENOSUMAB)/OSENVELT (DENOSUMAB-BMWO)

- **Warnings and precautions**
    - Same active ingredient: Beneficiaries receiving Xgeva should not receive Prolia.
    - While receiving Xgeva, supplementation with calcium and vitamin D may be necessary to treat or prevent hypocalcemia.
- **Prevention of skeletal-related events in beneficiaries with multiple myeloma OR bone metastases from solid tumors**
    - The drug is used for prevention of skeletal-related events in beneficiaries with multiple myeloma and in beneficiaries with bone metastases from solid tumors
- **Giant cell tumor of the bone**
    - The beneficiary must be an adult or at least 12 years of age and skeletally mature
    - The beneficiary's disease is unresectable or surgical resection is likely to result in severe morbidity
- **Hypercalcemia of malignancy**
    - The beneficiary must have a diagnosis of cancer (malignancy)
        - The beneficiary must have 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 trial on previous therapy with intravenous (IV) bisphosphonates (e.g., ibandronate or zoledronic acid); **OR**
        - The beneficiary has a documented contraindication^^ (see table below) or intolerance to intravenous (IV) bisphosphonates (e.g., ibandronate, pamidronate, zoledronic acid).

*Ineffective response is defined as one or more of the following:
• Decrease in T-score in comparison with baseline T-score from Bone Density scan
**High risk for fractures includes but is 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 smoker • History of oral glucocorticoids ≥5 mg/d of prednisone for >3 months (ever)
^^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 gastrointestinal disorder such as inability to swallow, • Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, etc.; **AND**
- **Prolia (denosumab)/Stoboclo (denosumab-bmwo)**
  - Disease response, as indicated by one or more of the following:
    - Absence of fractures
    - Increase in bone mineral density compared to pretreatment baseline
- **Xgeva (denosumab) / Osenvelt (denosumab-bmwo)**
  - Disease response, as indicated by the following:
    - **Multiple myeloma OR bone metastases from solid tumors**
      - Absence/delay in skeletal-related events
    - **Giant cell tumor of the bone**
      - Tumor response with disease stabilization or decrease in size or spread of tumor
    - **Hypercalcemia of malignancy**
      - Corrected serum calcium ≤ 11.5 mg/dL

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0897 – Injection, denosumab, 1 mg; 1 mg = 1 billable unit
- J3590 – Injection, denosumab-bmwo,

DURYSTA (BIMATOPROST IMPLANT)

Updated: 03/04/2025

INDICATIONS

Durysta is indicated for treatment of:

- **Open angle glaucoma (OAG)**
- **Ocular hypertension (OHT)**

CLINICAL CRITERIA

- The beneficiary is ≥ 18 years of age.
- The beneficiary has a diagnosis of open angle glaucoma (OAG) or ocular hypertension (OHT).
- The medication is prescribed by or in consultation with an ophthalmologist.
- The beneficiary is unable to manage glaucoma using eye drops (e.g., age-related decline in dexterity, visual impairment, etc.)
- The beneficiary has not previously received treatment with Durysta in the requested eye.
- The beneficiary does not have any of the following contraindications to Durysta:
  - Active or suspected ocular or periocular infection
  - Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' dystrophy)
  - History of corneal transplantation or endothelial cell transplant (e.g., Descemet's stripping automated endothelial keratoplasty [DSAEK])
  - Absent or ruptured posterior lens capsule.
  - Hypersensitivity to bimatoprost or to any other component of the product

APPROVAL DURATION

1 dose (one implant per treated eye; a total of two implants per beneficiary)

RENEWAL/REAUTHORIZATION

Cannot be renewed / reauthorized.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7351 - intracameral implant containing bimatoprost 10 mcg; 1 billable unit = 1mcg

ELAHERE (MIRVETUXIMAB SORAVTANSINE-GYNX)

Updated: 03/04/2025

BLACK BOX WARNING – OCULAR TOXICITY

Elahere can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.

- Documentation is required of an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of Elahere, every other cycle for the first 8 cycles, and as clinically indicated.
- Administration of prophylactic artificial tears and ophthalmic topical steroids recommended.
- Withhold Elahere for ocular toxicities until improvement and resume at the same or reduced dose or discontinue permanently based on severity.

INDICATIONS

Elahere is indicated for treatment of:

- **Epithelial ovarian, fallopian tube, or primary peritoneal cancer**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer
- The beneficiary is 18 years of age or older.
- The beneficiary is folate receptor-alpha (FRα) positive.
- The beneficiary's disease is platinum resistant.
- Previous therapy includes at least one to three prior systemic treatment regimens.
- Beneficiary does not have moderate to severe hepatic impairment (Child-Pugh Class B or C or total bilirubin > 1.5 ULN).
- The drug is prescribed by an oncologist.
- The beneficiary has a documented ophthalmological evaluation at baseline and is adhering to an eye care plan.

DOSAGE AND ADMINISTRATION

The recommended dose of Elahere is 6 mg/kg adjusted to ideal body weight and administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity.

PREMEDICATION AND REQUIRED EYE CARE

Note: To help mitigate risk and manage ocular adverse events and to support gynecologic oncology providers who may be less familiar with ocular adverse events, consultation and referral to an ophthalmologist and beneficiary adherence to the following eye care plan is recommended.

- **Ophthalmic exam**: Documentation is required of an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of Elahere, every other cycle for the first 8 cycles, and as clinically indicated.

- **Topical corticosteroid eye drops**: Administration of ophthalmic topical steroids is recommended. Initial prescription and all renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer first drop in each eye prior to each infusion.
- **Topical lubricating eye drops**: Administration of prophylactic artificial tears.
- **Ocular Toxicities**: Withhold Elahere for ocular toxicities until improvement and resume at the same or reduced dose. Discontinue Elahere for Grade 4 ocular toxicities.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Elahere 100 mg/20 mL (5 mg/mL) single-dose vial: 72903-0853-xx

ELAPRASE (IDURSULFASE)

Updated: 03/04/2025

INDICATIONS

Elaprase is indicated for treatment of:

- **Hunter syndrome (mucopolysaccharidosis II, MPS II)**

Elaprase has been shown to improve walking capacity in beneficiaries 5 years of age or older. In beneficiaries 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long-term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older.

CLINICAL CRITERIA

- The beneficiary is at least 16 months old
- The beneficiary has a diagnosis of Hunter syndrome (mucopolysacharidosis II)
- The beneficiary has documented deficiency in iduronate-2-sulfatase enzyme activity confirming a diagnosis of Hunter syndrome through enzyme or molecular (DNA-based) testing
- Baseline values for the following have been documented:
  - The beneficiary's weight dated within 1 month of the prior authorization request
  - The beneficiary's urinary glycosaminoglycan (uGAG)
  - For beneficiaries 6 years of age or older, one of the following:
    - 6-mnute walk test (6-MWT); **OR**
    - Percent predicted forced vital capacity (FVC)
  - For beneficiaries younger than 6 years of age, one of the following:
    - Spleen volume; **OR**
    - Liver volume; **OR**
    - Upper airway obstruction during sleep; **OR**
    - Cardiac status; **OR**
    - Growth velocity; **OR**
    - FVC; **OR**
    - 6-minute walk test
- Prescriber attestation of the following:
  - Absence of cognitive impairment; **AND**
  - No evidence of significant or progressive neurodevelopmental involvement; **AND**
  - The beneficiary is not on chronic invasive mechanical ventilation; **AND**
  - The beneficiary does not have a concomitant life-threatening or severe disease for which the long-term prognosis is unlikely to be influenced by enzyme replacement therapy (ERT) (e.g., neuroblastoma, leukemia etc.)

NOTE: For beneficiaries with evidence of significant or progressive neurodevelopmental involvement, this would indicate that the beneficiary has the severe form of Hunter syndrome (MPS IIA). Evidence is lacking to support the use of Elaprase in Hunter syndrome Type A, which is the more severe variant of

the disease. Beneficiaries in clinical studies were required to cooperate with pulmonary function tests, so as a result, only beneficiaries with the milder form of Hunter syndrome were enrolled.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity including anaphylactic and anaphylactoid reactions, antibody development and serious adverse reactions, acute respiratory complications, acute cardiopulmonary failure)
- The beneficiary does not have progressive or irreversible severe cognitive impairment
- The beneficiary has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - Beneficiaries 5 years of age or older: stabilization or improvement in percent predicted FVC or 6-minute walk test.
  - Beneficiaries < 5 years of age: spleen volume, liver volume or stabilization, or improvement in FVC or 6-MWT

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1743 – Injection, idursulfase, 1 mg; 1 mg = 1 billable unit

ELELYSO (TALIGLUCERASE ALFA)

Updated: 03/04/2025

INDICATIONS

Elelyso is indicated for treatment of:

- Gaucher disease Type 1

CLINICAL CRITERIA

Type 1 Gaucher's disease

- **Pediatric guidelines**
  - The beneficiary is at least 4 years of age.
  - The beneficiary has a documented diagnosis of Type 1 Gaucher disease.
- **Adults only guidelines (the beneficiary is 18 years of age or older)**:
  - The beneficiary's disease results in one or more of the following:
    - Anemia; **OR**
    - Moderate to severe hepatomegaly or splenomegaly; **OR**
    - Skeletal disease (e.g., lesions, remodeling defects or deformity of long bones, osteopenia/osteoporosis, etc.); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.); **OR**
    - Thrombocytopenia

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distention, diminished quality of life, etc.)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobinemia
  - Improvement in platelet counts

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3060 – Injection, taliglucerase alfa, 10 units; 1 billable unit = 10 units

ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL)

Updated: 11/17/2025

INDICATIONS

Elevidys is FDA-approved for:

- **Ambulatory Duchenne muscular dystrophy (DMD) in beneficiaries at least 4 years of age**

CLINICAL CRITERIA

- For the treatment of Duchenne muscular dystrophy (DMD) in beneficiaries who are ambulatory and have a confirmed mutation in the DMD gene
- The beneficiary has rAAVrh74 antibody titers <1:400.
- The beneficiary has had baseline testing of the following:
  - Presence of anti-AAVrh74 total binding antibodies
  - Liver enzyme/liver function test
  - Platelet counts and Troponin-I

EXCLUSIONS

- The beneficiary has any deletion in exon 8 or exon 9 in the DMD gene.
- The beneficiary has elevated anti-AAVrh74 total binding antibody titers ≥ 1:400

DOSAGE

Elevidys is supplied as a customized kit containing 10 to 70 single-dose vials. The total number of vials in each kit corresponds to the dosing requirement for the individual beneficiary, based on the beneficiary's body weight.

APPROVAL DURATION

Single-dose treatment

RENEWAL/REAUTHORIZATION

No renewal or reauthorization

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Unclassified biologics

ELLENCE (EPIRUBICIN)

Updated: 03/04/2025

INDICATIONS

- **Breast cancer**
  - Ellence is indicated for use as a component of adjuvant therapy in beneficiaries with evidence of axillary node tumor involvement following resection of primary breast cancer.

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- The beneficiary has diagnosis of breast cancer
- The beneficiary has evidence of axillary node tumor involvement following resection

NCCN RECOMMENDATIONS

- Bladder cancer
- Breast cancer
- Merkel cell carcinoma
- Soft tissue sarcoma

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9178 - Injection, epirubicin HCl, 2 mg

ELOXATIN (OXALIPLATIN)

Updated: 07/28/2025

INDICATIONS

Eloxatin (oxaliplatin) is indicated for:

- **Advanced Colorectal Cancer**
- **Adjuvant treatment of Stage III Colon Cancer** in beneficiaries who have undergone complete resection of the primary tumor

CLINICAL CRITERIA

† FDA approved indications

‡ Compendia recommended indications

Colorectal cancer †

- Used as neoadjuvant or adjuvant therapy; **OR**
- Used for unresectable, locally advanced or metastatic disease.

Pancreatic cancer (Off-label)

- Used as first-line treatment in the FOLFIRINOX (leucovorin, fluorouracil, irinotecan, and oxaliplatin) regimen for beneficiaries who meet all the following:
  - ECOG Performance Score is 0-1
  - Favorable comorbidity profile (see table below)
  - Beneficiary preference and as a support system for aggressive medical therapy
- As first-line treatment in the NALIRIFOX (liposomal irinotecan [Onivyde], 5-fluorouracil [5-FU]/leucovorin, and oxaliplatin) regimen in adult beneficiaries with metastatic pancreatic adenocarcinoma

Note: The following table is in reference to pancreatic cancer **ONLY**.

Comorbidity Profiles	Favorable	Relatively Favorable
Hemoglobin (without transfusion support)	≥ 10 g/dL	≥ 9 g/dL
Platelet count (without transfusion support)	≥ 100,000/microL	≥ 75,000/microL
Bilirubin	≤ 1.5 times ULN	≤ 1.5 times ULN
INR	≤ 1.5 times ULN	≤ 1.5 times ULN
Albumin	≥ 3 g/dL	≥ 3 g/dL
CrCl	≥ 60 mL/minute/1.73 m^2	≥ 60 mL/minute/1.73 m^2
Comorbid condition requiring ongoing active medical care (e.g., CHF, COPD, uncontrolled diabetes, neurologic disorders)	Absent	May be present, but not poorly controlled
ULN: upper limit of normal; INR: international normalized ratio; CrCl: creatinine clearance; CHF: congestive heart failure		

NCCN COMPENDIUM RECOMMENDATIONS

Oxaliplatin has wide-ranging off-label uses in treating multiple types of cancer. As these uses change frequently, consultation with current NCCN guidelines is recommended.

- **Ampullary adenocarcinoma ‡**
- **Anal carcinoma ‡**
- **Bladder cancer (non-urothelial and urothelial adenocarcinoma) ‡**
- **Classic Hodgkin lymphoma (cHL) ‡**
- **Esophageal and esophagogastric junction cancer (adenocarcinoma, squamous cell carcinoma) ‡**
- **Gastric adenocarcinoma ‡**
- **Hepatobiliary cancer ‡**
  - Intrahepatic cholangiocarcinoma (adenocarcinoma)
  - Extrahepatic cholangiocarcinoma (adenocarcinoma)
  - Gallbladder cancer (adenocarcinoma)
  - Hepatocellular carcinoma (adenocarcinoma)
- **Neuroendocrine tumors and adrenal tumors ‡**
  - Neuroendocrine tumors of the pancreas
  - Poorly differentiated (high grade)/large or small cell
  - Gastrointestinal tract carcinoid syndrome
- **Ovarian cancer ‡**
  - Fallopian tube, primary peritoneal, epithelial cancer
  - Mucinous carcinoma
- **Pancreatic adenocarcinoma ‡**
- **Primary cutaneous lymphomas ‡**
  - Mycosis fungoides/Sezary syndrome
  - Primary cutaneous CD30+ T-cell lymphoproliferative disorder
- **Small bowel adenocarcinoma ‡**
- **T-cell lymphomas**
  - Peripheral T-cell lymphomas
  - Adult T-cell leukemia/lymphoma
  - Hepatosplenic T-cell lymphoma
  - Extranodal NK/T-cell lymphoma
- **Testicular cancer ‡**

APPROVAL DURATION

Approval is for six months.

- **NOTE**: Per FDA and NCCN recommendations, administration of Oxaliplatin as adjuvant therapy for continued treatment is limited to up to 12 cycles (up to 6 months).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9263– Injection, oxaliplatin, 0.5 mg: 1 billable unit = 0.5 mg

EMPLICITI (ELOTUZUMAB)

Updated: 03/11/2025

INDICATIONS

Empliciti is indicated for treatment of:

- **Multiple Myeloma**

CLINICAL CRITERIA

- The drug is prescribed by an oncologist.
- The beneficiary is 18 years of age or older.
- The beneficiary has a diagnosis of relapsed or progressive disease.
- The drug is **used in combination with lenalidomide (Revlimid) and dexamethasone** for treatment of adult beneficiaries with multiple myeloma who have received one to three prior therapies; **OR**
  - The drug is **used in combination with pomalidomide (Pomalyst) and dexamethasone** for treatment of adult beneficiaries who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor, (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], etc.)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, infections, second primary malignancies, hepatotoxicity, etc).

BILLING/CODING INFORMATION

J9176 – Injection, elotuzumab, 1 mg; 1 billing unit = 1 mg

ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI)

Updated: 02/20/2025

INDICATIONS

Enhertu is indicated for treatment of:

- **HER2-positive breast cancer**
- **HER2-positive gastric / gastroesophageal junction adenocarcinoma**

CLINICAL CRITERIA

- Must be prescribed by or in consultation with an oncologist.
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and monitored regularly for need to modify the dose or discontinue the drug permanently.
- For treatment of adult beneficiaries with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2 based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine], Perjeta [pertuzumab]) either:
  - In the metastatic setting; **OR**
  - In the neoadjuvant or adjuvant setting in beneficiaries who have developed disease recurrence during or within six months of completing therapy
- For treatment of adult beneficiaries with unresectable or metastatic:
  - Hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer that has progressed on one or more endocrine therapies in the metastatic setting
  - HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer in beneficiaries who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.
    - **Note**: Chemotherapy does NOT include endocrine therapy or CDK 4/6 inhibitors like palbociclib (Ibrance).
- For treatment of adult beneficiaries with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations and who have received a prior systemic therapy.
- For treatment of adult beneficiaries with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.
- For treatment of adult beneficiaries with unresectable or metastatic HER2-postive (ICH 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.

- Absence of significant decrease in left ventricular ejection fraction (LVEF)
  - LVEF should be assessed prior to initiation of Enhertu and monitored regularly for need to modify the dose or discontinue the drug permanently.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9358 - Injection, fam-trastuzumab deruxtecan-nxki, 1 mg; 1 billable unit = 100 mg

ENTYVIO (VEDOLIZUMAB)

Updated: 03/11/2025

INDICATIONS

Entyvio is indicated for treatment of adult and pediatric beneficiaries with:

- **Crohn's disease**
- **Ulcerative colitis**

CLINICAL CRITERIA

- The beneficiary is 6 years of age or older
- The drug prescribed by or in consultation with a specialist in gastroenterology.
- The beneficiary is free of any active, severe infections
- The beneficiary is not on concurrent treatment with a biologic response modifier (e.g., etanercept, adalimumab, certolizumab, golimumab, infliximab, natalizumab, etc.)

Crohn's disease

- The beneficiary has documented moderate to severe disease

Ulcerative colitis

- The beneficiary has documented moderate to severe disease

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- **Crohn's disease**
  - Disease response, as indicated by improvement in signs and symptoms compared to baseline (e.g., 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, use of anti-diarrheal drugs, or an improvement on a disease activity scoring tool)
- **Ulcerative colitis**
  - Disease response, as indicated by improvement in signs and symptoms compared to baseline (e.g., stool frequency, rectal bleeding, or endoscopic activity, or an improvement on a disease activity scoring tool)

DOSAGE AND ADMINISTRATION

Per FDA prescribing indications, before initiating Entyvio, beneficiary immunizations should be updated according to current immunization guidelines.

BILLING/CODING INFORMATION

Applicable Procedure Codes

J3380 - Injection, vedolizumab, 1 mg; 1 billable unit = 1 mg

EPKINLY (EPCORITAMAB-BYSP)

Updated: 11/20/2025

INDICATIONS

Epkinly is indicated for treatment of

- **Relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)**
- **Follicular lymphoma (FL)**

CLINICAL CRITERIA

- The drug is prescribed by or in consultation with an oncologist or hematologist.

Diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma

- For treatment of adult beneficiaries with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

Follicular lymphoma

- As monotherapy for treatment of adult beneficiaries with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy; **OR**
  - In combination with lenalidomide and rituximab for relapsed or refractory follicular lymphoma (FL)

DOSAGE AND ADMINISTRATION

The recommended regimen consists of Epkinly administered subcutaneously in 28-day cycles until disease progression or unacceptable toxicity.

DLBCL and High-grade B-cell Lymphoma			
Cycle of Treatment	**Day of Treatment**	**Dose of Epkinly**	
Cycle 1	1	Step-up dose 1	0.16 mg
	8	Step-up dose 2	0.8 mg
	15	First full dose	48 mg
	22	48 mg	
Cycle 2 and 3	1, 8, 15, and 22	48 mg	
Cycle 4 to 9	1 and 15	48 mg	
Cycle 10 and beyond	1	48 mg	
Follicular Lymphoma			
Cycle of Treatment	**Day of Treatment**	**Dose of Epkinly**	
Cycle 1	1	Step-up dose 1	0.16 mg
	8	Step-up dose 2	0.8 mg
	15	First full dose	48 mg
	22	48 mg	
Cycle 2 and 3	1, 8, 15, and 22	48 mg	
Cycle 4 to 9	1 and 15	48 mg	

Cycle 10 and beyond	1	48 mg

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Beneficiary does not show evidence of progressive disease while on therapy or unacceptable toxicity.
  - Unacceptable toxicity from the drug includes cytokine release syndrome (CRS), serious neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS), serious infections (including bacterial, fungal, or viral), severe neutropenia/febrile neutropenia, severe thrombocytopenia, etc.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Subcutaneous injection, epcoritamab-bysp.

ERBITUX (CETUXIMAB)

Updated: 03/11/2025

INDICATIONS

Erbitux is indicated for treatment of:

- **Squamous cell carcinoma of the head and neck (SCCHN)**
- **Colorectal cancer (CRC)**

CLINICAL CRITERIA

- The beneficiary is 18 years or older.
- Must be prescribed by an oncologist or hematologist.
- The drug may be used as single agent or in combination with radiation or with chemotherapy.

Colorectal Cancer (CRC)

- The beneficiary has diagnosis of metastatic, unresectable, or medically inoperable disease.
- The beneficiary is BRAF V600E wild type (negative for mutation), and drug is being used:
  - In combination with FOLFIRI (leucovorin, fluorouracil, and irinotecan) for first-line treatment; **OR**
  - In combination with either an irinotecan- or oxaliplatin-containing regimen; **OR**
  - As a single agent in a beneficiary who is unable to tolerate irinotecan or who has experienced disease progression following oxaliplatin- and irinotecan-containing regimens; **OR**
  - The beneficiary is BRAF positive and the drug is being used in combination with Braftovi (encorafenib).

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- Used in one of the following regimens:
  - In combination with radiation therapy for regionally or locally advanced disease.
  - For treatment of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with fluorouracil.
  - For treatment of recurrent or metastatic squamous cell carcinoma of the head and neck that is progressing after platinum-based therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary continues to meet the approved indication
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, electrolyte abnormalities, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9055 – Injection, cetuximab, 10 mg; 1 billable unit = 10 mg

EVENITY (ROMOSOZUMAB-AQQG)

Updated: 03/11/2025

INDICATIONS

Evenity is indicated for treatment of

- **Osteoporosis in postmenopausal women at high risk for fracture**

CLINICAL CRITERIA

- The beneficiary must be at a high risk for fracture
- The beneficiary must be postmenopausal
- The beneficiary has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Bone mineral density (BMD) T-score ≤ 2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **OR**
  - History of one of the following resulting from minimal trauma:
    - Vertebral compression fracture
    - Fracture of the hip
    - Fracture of the distal radius
    - Fracture of the pelvis
    - Fracture of the proximal humerus; **OR**
  - BMD T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%.
- Documentation of failure, contraindication, or intolerance to oral bisphosphonates or intravenous bisphosphonate therapy (e.g., alendronate, risedronate, ibandronate, or zoledronic acid).
- The beneficiary is not receiving Evenity in combination with any of the following:
  - Parathyroid hormone analogs (e.g., Forteo, Tymlos)
  - RANK ligand inhibitors (e.g., Prolia, Xgeva)
- Confirmation that the beneficiary is receiving calcium and vitamin D supplementation if dietary intake is inadequate
- The beneficiary does not have hypocalcemia

APPROVAL DURATION

Per FDA, duration of use is limited to 12 monthly doses.

RENEWAL/REAUTHORIZATION

May not be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3111 − Injection, romosozumab-aqqg, 1 mg; 1 billable unit = 1 mg

EXONDYS 51 (ETEPLIRSEN)

Updated: 03/11/2025

INDICATIONS

Exondys 51 is FDA approved for:

- **Duchenne muscular dystrophy (DMD)**

CLINICAL CRITERIA

- Diagnosis of Duchenne muscular dystrophy (DMD) by or in consultation with a neurologist with expertise in the diagnosis of DMD
- Submission of medical records confirming that the mutation of the DMD gene is amenable to exon 51 skipping
- The beneficiary has been on a stable dose of oral corticosteroids, unless contraindicated or intolerance, for at least 3 months
- The beneficiary is not concurrently treated with other DMD antisense oligonucleotides (e.g., casimersen [Amondys 45], golodirsen [Vyondys 53], or viltolarsen [Viltepso]).
- Baseline documentation within the last 30 days of the following:
  - Pulmonary function test (PFT)
  - End-tidal capnography (ETCo2)
  - Timed 30-foot walk
  - Time to go up 4 stairs
  - Brook scale for upper extremity
  - Vignos scale for lower extremity

APPROVAL DURATION

Approval is for 6 months at a time.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., renal toxicity/proteinuria, etc.)
- Follow-up functional test results must show stabilization or improvement of beneficiary function compared to baseline measures.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1428 – Injection, eteplirsen, 10 mg

FABRAZYME (AGALSIDASE BETA)

Updated: 03/17/2025

INDICATIONS

Fabrazyme is indicated for treatment of:

- **Fabry disease (alpha-galactosidase A deficiency)**

CLINICAL CRITERIA

Fabry Disease

- The beneficiary is 2 years of age or older.
- The beneficiary has a documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, or cultured cells; **OR**
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3); **OR**
  - Pathogenic mutations in the GALA/GLA gene detected by molecular genetic testing; **AND**
- Baseline value for plasma GL-3 or GL-3 inclusions

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response to treatment, as defined by a reduction in plasma GL-3 or GL-3 inclusions compared to pre-treatment baseline.
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, infusion reactions, compromised cardiac function)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0180 – Injection, agalsidase beta, 1 mg; 1 billable unit = 1 mg

FASENRA (BENRALIZUMB)

Updated: 03/17/2025

INDICATIONS

FDA Approved Indications:

- **Severe asthma with an eosinophilic phenotype**
- **Eosinophilic granulomatosis with polyangiitis (EGPA)**

CLINICAL CRITERIA

Severe asthma with an eosinophilic phenotype

- The beneficiary must be 6 years of age or older
- The beneficiary must have severe* asthma (see table below)
- The beneficiary must have asthma with an eosinophilic phenotype, defined as blood eosinophils ≥ 150 cells/microliter within 6 weeks of dosing
- The drug must be used for add-on maintenance treatment in a beneficiary who is regularly receiving BOTH of the following:
  - High-dose inhaled corticosteroids
  - An additional controller medication (e.g., long-acting beta agonist, etc.)
- The beneficiary must have ONE of the following:
  - Two or more exacerbations in the previous year
  - Requirement of daily oral corticosteroids (for at least 3 days in addition to the regular maintenance therapy defined above)

*Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times daily • Extreme limitation of normal activities • Lung function (percent predicted FEV1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

- The beneficiary is 18 years of age or older
- The beneficiary has a diagnosis of EGPA

APPROVAL DURATION

Authorization is provided for 6 months.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., parasitic infection, severe hypersensitivity reactions, etc.)
- Clinical benefit to treatment, as evidenced by:
  - Improvement in asthma symptoms or asthma exacerbations, as evidenced by a decrease in one or more of the following:
    - Use of systemic corticosteroids
    - A two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - Emergency department visits
    - Unscheduled visits to health care provider
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0517 − Injection, benralizumab, 1 mg: 1 billable unit = 1 mg

FASLODEX FULVESTRANT, FULVESTRANT (TEVA), FULVESTRANT (FRESENIUS KABI)

Updated: 03/17/2025

INDICATIONS

Faslodex is indicated for treatment of:

- Hormone receptor (HR)-positive, human epidermal growth receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy
- HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy
- HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib (Kisqali), as initial endocrine based therapy or following disease progression on endocrine therapy
- HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib (Ibrance) or abemaciclib (Verzenio) in women with disease progression after endocrine therapy

CLINICAL CRITERIA

NCCN RECOMMENDED INDICATIONS

Endometrial carcinoma (off-label)

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary's disease is classified as grade 1 or 2 endometrioid carcinoma
- The drug is prescribed in one of the following ways:
  - For recurrent or metastatic disease
  - For stage II disease, in combination with sequential external beam radiation therapy
  - For stage IIIA or higher disease
  - For disease not suitable for primary surgery

Ovarian, fallopian tube, and primary peritoneal cancer (off-label)

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary's disease is classified as low-grade serous carcinoma.

Premenopausal receiving ovarian ablation or suppression (off-label)

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary's disease is recurrent unresectable (local or regional); **OR**
- The beneficiary's disease is stage IV

Uterine sarcoma (off-label)

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary's disease is classified in one of the following ways:
  - Low-grade endometrial stomal sarcoma
  - Adenosarcoma without sarcomatous overgrowth

- HR-positive uterine leiomyosarcoma

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., bleeding abnormalities, increased exposure in beneficiaries with hepatic impairment, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9395 – Injection, fulvestrant, 25 mg; 1 billable unit = 25 mg
- J9393 – Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg
- J9394 – Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg

FOLOTYN (PRALATREXATE INJECTION)

Updated: 04/03/2025

INDICATIONS

Folotyn is indicated for the treatment of:

- **Relapsed or refractory peripheral T-cell lymphoma (PTCL)**

CLINICAL CRITERIA

FDA RECOMMENDED PRESCRIBING INDICATIONS

- Initiation of pralatrexate (Folotyn) is indicated for use in treatment of **ANY** of the following PTCL subtypes:
  - Peripheral T-cell lymphoma not otherwise specified
  - Anaplastic large cell lymphoma
  - Angioimmunoblastic T-cell lymphoma
  - Enteropathy-associated T-cell lymphoma
  - Monomorphic epitheliotropic intestinal T-cell lymphoma
  - Nodal peripheral T-cell lymphoma with TFH phenotype
  - Follicular T-cell lymphoma
- The drug is prescribed by or in consultation with an oncologist or hematologist
- The drug is used as single therapy
- The beneficiary is 18 years of age or older
- The beneficiary is receiving vitamin B12 1 mg intramuscularly every 8-10 weeks
- The beneficiary is receiving folic acid 1 to 1.25 mg orally once weekly

NCCN RECOMMENDED OFF-LABEL INDICATIONS

- Initiation of pralatrexate (Folotyn) is indicated for use in treatment of **ANY** of the following NCCN recommended indications:
  - Primary cutaneous T-cell lymphomas:
    - Mycosis fungoides or Sézary syndrome
    - Primary cutaneous anaplastic large cell lymphoma (ALCL) with multimodal lesions, or cutaneous ALCL with regional nodes
  - Other T-cell lymphomas:
    - Adult T-cell leukemia/lymphoma (ATLL) after failure of first-line therapy
    - Extranodal NK/T-cell lymphoma (NKTL), nasal type, following asparaginase-based therapy
    - Hepatosplenic gamma-delta T-cell lymphoma (HGTL) after failure of 2 prior treatment regimens
    - Breast implant-associated anaplastic large cell lymphoma (BI-ALCL) after failure of first-line therapy
    - Peripheral T-cell lymphoma
    - Adult T-cell leukemia/lymphoma

- The drug is prescribed by or in consultation with an oncologist or hematologist
- The drug is used as single therapy
- The beneficiary is 18 years of age or older
- The beneficiary is receiving vitamin B12 1 mg intramuscularly every 8-10 weeks
- The beneficiary is receiving folic acid 1 to 1.25 mg orally once weekly

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease response with treatment and the beneficiary does not show evidence of progressive disease during treatment with pralatrexate.
- Absence of unacceptable toxicity from pralatrexate (e.g., myelosuppression, mucositis, severe dermatologic reactions, tumor lysis syndrome, toxic epidermal necrolysis, etc.)

RECOMMENDED DOSING

Single dose vial: 20 mg/1 mL or 40 mg/2 mL

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9307 - Injection, pralatrexate, 1 mg, 1 billable unit = 1 mg

FUSILEV (LEVOLEUCOVORIN)

Updated: 03/17/2025

INDICATIONS

Fusilev is indicated for treatment of:

- Rescue after high-dose methotrexate therapy in adult and pediatric beneficiaries with osteosarcoma
- Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination in adult and pediatric beneficiaries.
- Treatment of adults with metastatic colorectal cancer in combination with fluorouracil-based regimens

CLINICAL CRITERIA

- The beneficiary is 6 years of age or older.
  - (Except in colorectal cancer diagnosis; FDA approval is for adults only)

Colorectal Cancer

- The beneficiary is 18 years of age and older.
- The drug must be used in combination with fluorouracil-based regimens in the palliative treatment of beneficiaries with advance metastatic colorectal cancer.

EXCLUSION

Fusilev is not approved for pernicious anemia and megaloblastic anemias secondary to lack of vitamin B12.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, seizures, and severe gastrointestinal disorders such as stomatitis, severe diarrhea, and severe nausea and vomiting)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0641 – Injection, levoleucovorin calcium, 0.5 mg = 1 billable unit

GAMIFANT (EMAPALUMAB-LZSG)

Updated: 09/27/2025

INDICATIONS

Hemophagocytic Lymphohistiocytosis (HLH)

- Treatment of adult and pediatric (newborn and older) beneficiaries with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance to conventional HLH therapy.
- Treatment of adult and pediatric (newborn and older) beneficiaries with HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic juvenile idiopathic arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

CLINICAL CRITERIA

- The beneficiary has a definitive diagnosis of HLH as indicated by the following:
  - A 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**
  - The beneficiary has at least **five** of the following documented conditions:
    - Prolonged fever (> 7 days)
    - Splenomegaly
    - Cytopenia 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 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
  - The beneficiary has active, primary disease that is refractory, recurrent, or progressive during treatment with conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporin A, anti-thymocyte globulin, etc.) unless the beneficiary is intolerant to conventional HLH therapy.
  - The beneficiary has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment.
  - The drug is used in combination with dexamethasone
    - **Note**: Beneficiaries currently on oral cyclosporin A, intrathecal methotrexate, or glucocorticoids may continue on therapy while treated with emapalumab.
  - The beneficiary is a candidate for stem cell transplantation.
  - Gamifant is being used as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Experienced an improvement in HLH abnormalities as evidenced by one of the following:
  - Complete response, defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > $1x10^9$/L, platelets > 100 x 10^9/L, ferritin < 2,000 µg/L, fibrinogen > 1.50 g/L, D-dimer < 500 ug/L, normal CNS symptoms, no worsening of sCD25 > two-fold baseline); **OR**
  - Partial response defined as normalization of ≥ 3 HLH abnormalities (including CNS abnormalities); **OR**
  - HLH improvement, defined as improvement by at least 50% from baseline of ≥ 3 HLH clinical and laboratory conditions (including CNS involvement).
- Absence of unacceptable toxicity from Gamifant (e.g., serious infections [including mycobacteria, Herpes Zoster virus, and Histoplasma Capsulatum], infusion-related reactions [including drug eruption, pyrexia, rash, erythema, and hyperhidrosis], etc.)
- Monitoring for presence of TB and other infections (e.g., adenovirus, EBV, and CMV) as clinically indicated. Repeat latent TB and other infection testing should be focused on beneficiaries who have new risk factors for these infections since their last screening.
- The beneficiary continues to require therapy for treatment of HLH until HSCT is performed or until unacceptable toxicity.
- Dose escalation (up to the maximum dose and frequency specified below) requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as demonstrating at least ONE of the following:
  - Fever – persistence or recurrence
  - Platelet count
    - If baseline < 50,000/mm^3 and no improvement to >50,000/mm^3
    - If baseline > 50,000/mm^3 and less than 30% improvement
    - If baseline > 100,000/mm^3 and decrease to < 100,000/mm^3
  - Neutrophil count
    - If baseline < 500/mm^3 and no improvement to > 500/mm^3
    - If baseline > 500 -1000/mm^3 and decrease to < 500/mm^3
    - If baseline 1000-1500/mm^3 and decrease to < 1000/mm^3
  - Ferritin (ng/mL)
    - If baseline ≥ 3000 ng/mL and < 20% decrease
    - If baseline < 3000 ng/mL and any increase to > 3000 ng/mL
  - Splenomegaly – any worsening
  - Coagulopathy (both D-dimer and fibrinogen must apply)
    - D-Dimer
      - If abnormal at baseline and no improvement
    - Fibrinogen (mg/dL)
      - If baseline levels ≤ 100 mg/dL and no improvement

- If baseline levels > 100 mg/dL and any decrease to < 100 mg/dL

DOSAGE/ADMINISTRATION

Indication: HLH:

- Administer initial doses of 1 mg/kg, intravenously over one hour, twice per week (every three to four days). Titrate doses up to 10 mg/kg as follows:
  - On day 3, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider, increase to 3 mg/kg.
  - From day 6 and onwards, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider on the 3 mg/kg dose, increase to 6 mg/kg.
  - From day 9 and onwards, if an unsatisfactory improvement in clinical condition is assessed by the healthcare provider on the 6 mg/kg dose, increase to 10 mg/kg.
- Used in combination with dexamethasone at a daily dose of at least 5-10 mg/m^2 starting the day before Gamifant treatment begins.
- Administer until hematopoietic stem cell transplantation (HSCT) is performed or unacceptable toxicity.
- Discontinue when the beneficiary no longer requires therapy for the treatment of HLH.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9210 − Injection, emapalumab-lzsg, 1 mg; 1 billable unit = 1 mg

GAZYVA (OBINUTUZUMAB)

Updated: 10/21/2025

INDICATIONS

Gazyva is indicated for treatment of:

- **Chronic lymphocytic leukemia (CLL)**
- **Follicular lymphoma (FL)**
- **Lupus nephritis (LN)**

CLINICAL CRITERIA

- The drug must be prescribed by a hematologist or oncologist.
- The beneficiary is 18 years of age or older.
- The beneficiary does not have an active infection.
- The beneficiary has not received a live vaccine in the preceding 28 days.

Chronic lymphocytic leukemia (CLL)

- In combination with chlorambucil, for the treatment of beneficiaries with previously untreated chronic lymphocytic leukemia (CLL).

Follicular lymphoma (FL)

- In combination with bendamustine followed by GAZYVA monotherapy, for the treatment of beneficiaries with follicular lymphoma (FL) who relapsed after or are refractory to a rituximab-containing regimen.
- In combination with chemotherapy followed by GAZYVA monotherapy, for the treatment of adult beneficiaries with previously untreated stage II bulky, III or IV follicular lymphoma (FL) who have achieved at least a partial remission.

Lupus nephritis (LN)

- For the treatment of adult beneficiaries with active lupus nephritis (LN) who are receiving standard therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., progressive multifocal leukoencephalopathy [PML], hepatitis B reactivation, severe neutropenia or febrile neutropenia, severe thrombocytopenia, severe infusion reactions, hypersensitivity reactions including serum sickness, tumor lysis syndrome, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9301 – Injection, obinutuzumab, 10 mg: 1 billable unit = 10 mg

GIVLAARI (GIVOSIRAN)

Updated: 03/17/2025

INDICATIONS

Givlaari is indicated for treatment of

- **Acute hepatic porphyria (AHP)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has a confirmed diagnosis of acute hepatic porphyria (AHP)
- The beneficiary has elevated urinary or plasma PBG (urinary porphobilinogen) or ALA (urinary aminolevulinic acid) values within the past year.
- The beneficiary is not prophylactically using hemin while on the requested treatment (this does NOT include hemin treatment for acute attacks)

EXCLUSIONS (BASED ON ENVISION CLINICAL TRIAL ELIGIBILITY AND EXCLUSIONS)

- The beneficiary is pregnant.
  - Female beneficiaries of childbearing age must have a negative serum pregnancy test, not be nursing, and use acceptable contraception.
- Liver transplantation is anticipated
- The beneficiary has active HIV, hepatitis C virus, or hepatitis B virus infections
- History of recurrent pancreatitis

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has a positive response, defined as ≥ 70% reduction from baseline in porphyria attacks that required hospitalization, urgent healthcare visits, or intravenous hemin administration at home.
- No unacceptable toxicity (e.g., anaphylactic reactions, hepatic toxicity [severe or clinically significant transaminase elevations], renal toxicity, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J-3590 – Injection, givosiran

GRANULOCYTE COLONY-STIMULATING FACTORS

Updated: 03/06/2025

INDICATIONS

FILGRASTIM

- **Granix** (tbo-filgrastim)
- **Nivestym** (filgrastim-aafi)
- **Neupogen** (filgrastim)
- **Releuko** (filgrastim-ayow)
- **Zarxio** (filgrastim-sndz)
- **Filgrastim granulocyte colony-stimulating factors are FDA approved to:**
  - Decrease the incidence of infection, as manifested by febrile neutropenia in beneficiaries with non-myeloid malignancies who are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe febrile neutropenia
  - Reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of beneficiaries with acute myeloid leukemia (AML) and chronic myeloid leukemia (CML).
  - Reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in beneficiaries with non-myeloid malignancies who are undergoing myeloablative chemotherapy followed by bone marrow transplantation
  - Mobilize hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
  - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic beneficiaries with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
  - Increase survival in beneficiaries who are acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)
  - Treatment of neutropenia in solid organ transplant recipients.
- **Filgrastim is NOT FDA approved or considered medically necessary for:**
  - Splenic rupture
  - Acute respiratory distress syndrome
  - Sickle cell crisis
  - WBC count greater than 100 x 10^9/L (100,000 K/mL) or ANC greater than 10 x 10^9/L (10,000 K/mL)
  - Capillary leak syndrome
  - Aortitis
  - Cutaneous vasculitis
  - Within 24 hours before/after chemotherapy
  - Routine use as prophylaxis with chemotherapy regimens associated with low risk for febrile neutropenia.

        - **Note**: G-CSFs may be considered for beneficiaries who are receiving low-risk (< 10%) regimens who have 2 or more beneficiary-related risk factors. Use of G-CSF in this setting is based on clinical judgment.
    - Routine use as prophylaxis with chemoradiation

PEGFILGRASTIM

- **Neulasta** (pegfilgrastim)
- **Fulphila** (pegfilgrastim-jmdb)
- **Ziextenzo** (pegfilgrastim-bmez)
- **Udenyca** (pegfilgrastim-cbqv)
- **Nyvepria** (pegfilgrastim-apgf)
- **Stimufend** (pegfilgrastim-fpgk)
- **Fylnetra** (pegfilgrastim-pbbk)
- **Rolvedon** (eflapegrastim-xnst)
- **Pegfilgrastim granulocyte colony-stimulating factors are FDA approved to:**
    - Decrease the incidence of infection, as manifested by febrile neutropenia, in beneficiaries with non-myeloid malignancies who are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
    - Increase survival in beneficiaries acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome).
- **Pegfilgrastim is NOT FDA approved or considered medically necessary for:**
    - Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation
    - Stem cell transplantation
    - Splenic rupture
    - Acute respiratory distress syndrome
    - Sickle cell crisis
    - WBC count greater than 100 x 10^9/L (100,000 K/mL) or ANC greater than 10 x 10^9/L (10,000 K/mL)
    - Capillary leak syndrome
    - Aortitis
    - Cutaneous vasculitis
    - Administration within 24 hours after chemotherapy or within 14 days prior to the next chemotherapy cycle
    - Routine use as prophylaxis with chemotherapy regimens associated with low risk for febrile neutropenia.
        - **Note**: G-CSFs may be considered for beneficiaries receiving low-risk (< 10%) regimens who have 2 or more beneficiary-related risk factors. Use of G-CSF in this setting is based on clinical judgment.
    - Routine use as prophylaxis with chemoradiation

CLINICAL CRITERIA

BENEFICIARIES RECEIVING INDUCTION OR CONSOLIDATION CHEMOTHERAPY FOR AML OR CML

- **Filgrastim** may be approved for beneficiaries set to receive induction or consolidation chemotherapy for acute myeloid leukemia (AML) or chronic myeloid leukemia (CML):
- If requirements are met, the request will be approved for 6 months

PRIMARY PREVENTION OR TREATMENT OF FEBRILE NEUTROPENIA IN BENEFICIARIES RECEIVING MYELOSUPPRESSIVE CHEMOTHERAPY

- **Filgrastim** or **pegfilgrastim** may be approved for the primary prevention or treatment of febrile neutropenia if ONE of the following are met:
  - The chemotherapy regimen has a **high (> 20%)** risk of febrile neutropenia; **OR**
  - The chemotherapy regimen has an **intermediate (10–20%)** risk of febrile neutropenia and the beneficiary meets ONE of the following risk factors:
    - Prior chemotherapy or radiation therapy to pelvis or other areas important for bone marrow reserve
    - Persistent neutropenia (ANC 1000/mm^3 or less)
    - Bone marrow involvement by tumor
    - Recent surgery or open wounds
    - Liver dysfunction (bilirubin > 2.0 mg/dL)
    - Renal dysfunction (eGFR < 50 mL/min/1.73m^2)
    - The beneficiary is > 65 years of age and is receiving full chemotherapy dose intensity
    - Poor performance status or human immunodeficiency virus (HIV) infection (particularly in beneficiaries with low CD4 counts)
  - The beneficiary has experienced treatment delay of curative chemotherapy due to a dose-limiting neutropenic event, with the same dose and schedule planned for future cycles.
- **Note**: G-CSFs may be considered for beneficiaries receiving regimens with **low risk (< 10%)** of febrile neutropenia who have 2 or more beneficiary-related risk factors. Use of G-CSF in this setting is based on clinical judgment (NCCN guidelines v.1.2025).
- If requirements are met, the request may be approved for 6 months.

SECONDARY PREVENTION OF FEBRILE NEUTROPENIA IN BENEFICIARIES RECEIVING MYELOSUPPRESSIVE CHEMOTHERAPY

Filgrastim or **pegfilgrastim** may be approved for the secondary prevention of febrile neutropenia if ONE of the following are met:

- The beneficiary has experienced febrile neutropenia with a previous cycle of similar chemotherapy, with the same dose and schedule planned for future cycles; **OR**
- The beneficiary has experienced treatment delay of curative chemotherapy due to a dose-limiting neutropenic event, with the same dose and schedule planned for future cycles; **OR**
- The beneficiary has experienced treatment delay of palliative chemotherapy due to a dose-limiting neutropenic event, and dose reduction or a delay in frequency of subsequent chemotherapy cycles is not recommended

- If requirements are met, the request will be approved for 6 months.

TREATMENT OF FEBRILE NEUTROPENIA

Filgrastim may be approved for the treatment of febrile neutropenia if BOTH of the following criteria are met:

- The beneficiary has been diagnosed with febrile neutropenia; **AND**
- The beneficiary has ONE of the following high-risk factors:
  - The beneficiary is > 65 years of age
  - Hospitalization for febrile neutropenia
  - Sepsis syndrome
  - Invasive fungal infection
  - Clinically documented infection, such as pneumonia
  - Prolonged or profound neutropenia
  - History of prior episodes of febrile neutropenia
- If requirements are met, the request will be approved for 6 months.

BENEFICIARIES WITH CANCER UNDERGOING BONE MARROW TRANSPLANTATION

- **Filgrastim** may be approved for 6 months.

BENEFICIARIES UNDERGOING PERIPHERAL BLOOD PROGENITOR CELL COLLECTION THERAPY

- **Filgrastim** may be approved for 6 months.

BENEFICIARIES WITH SEVERE CHRONIC NEUTROPENIA (SCN)

- **Filgrastim** may be approved after confirmation of diagnosis of SCN by evaluating serial CBCs with differential platelet counts.
- The request will be approved for 6 months.

BENEFICIARIES ACUTELY EXPOSED TO MYELOSUPPRESSIVE DOSES OF RADIATION

- **Filgrastim** or **Pegfilgrastim** may be approved for hematopoietic subsyndrome of acute radiation syndrome when beneficiaries are exposed to lethal doses of total-body radiation but not doses high enough to lead to certain death as a result of injury to other organs.
- The request will be approved for 6 months.

TREATMENT OF NEUTROPENIA IN SOLID ORGAN TRANSPLANT RECIPIENTS

- **Filgrastim** may be approved to increase neutrophil counts in solid organ transplant recipients.
- The request will be approved for 6 months.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- There is documentation that the beneficiary continues to show a positive clinical response to therapy
- Absence of unacceptable toxicity from the drug (e.g., splenic rupture, acute respiratory distress syndrome [ARDS], serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis,

leukocytosis, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1442 – Injection, filgrastim (Neupogen), 1 microgram
- J1447 – Injection, tbo-filgrastim (Granix), 1 microgram
- Q5101 – Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 microgram
- Q5110 – Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
- Q5125 – Injection, filgrastim-ayow, biosimilar, (Releuko), 1 microgram
- J2506 – Injection, pegfilgrastim, (Neulasta only) excludes biosimilar, 0.5 mg = 1 billable unit
- Q5108 – Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg; 1 billable unit = 0.5 mg
- Q5111 – Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg; 1 billable unit = 0.5 mg
- Q5120 – Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg; 1 billable unit = 0.5 mg
- Q5122 – Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg; 1 billable unit = 0.5 mg
- Q5127 – Injection, pegfilgrastim-fpgk, biosimilar, (Stimufend), 0.5 mg; 1 billable unit = 0.5 mg
- Q5130 – Injection, pegfilgrastim-pbbk, biosimilar, (Fylnetra), 0.5 mg; 1 billable unit = 0.5 mg
- J1449 – Injection, eflapegrastim-xnst, 0.1 mg; (Rolvedon), 0.1 mg; 1 billable unit = 0.1 mg

HALAVEN (ERIBULIN)

Updated: 03/17/2025

INDICATIONS

Halaven is indicated for treatment of:

- **Metastatic breast cancer**
- **Unresectable or metastatic liposarcoma**

CLINICAL CRITERIA

- The beneficiary is 18 years or older.

Breast Cancer

- The drug is used as subsequent therapy for metastatic disease in beneficiaries who have previously received therapy with an anthracycline and a taxane in either the adjuvant or metastatic setting.

Liposarcoma

- The beneficiary has unresectable or metastatic or recurrent disease.
- The beneficiary received prior anthracycline-based therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as defined by lack of disease progression, improvement in tumor size, or improvement in beneficiary symptoms.
- Absence of unacceptable toxicity from the drug (e.g., severe QT-prolongation, severe neutropenia [ANC <5000/m^3], peripheral neuropathy, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9179 – Injection, eribulin mesylate, 0.1 mg; 1 billable unit = 0.1 mg

HEMLIBRA (EMICIZUMAB-KXWH)

Updated: 11/26/2024

INDICATIONS

Hemophilia A (congenital factor VIII deficiency)

- Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric beneficiaries ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

CLINICAL CRITERIA

APPROVAL CONSIDERATION FOR HEMOPHILIA A WITH INHIBITORS:

- The beneficiary has a documented diagnosis of congenital hemophilia AWITH inhibitors and ONE of the following:
  - High factor VIII inhibitor titer (≥5 Bethesda units per mL [BU]); **OR**
  - Factor VIII inhibitor titer < 5 BU/mL with inadequate response to high dose factor.
- Hemlibra is prescribed by or in consultation with a hematologist or hemophilia specialist.
- The beneficiary has documentation for use of Hemlibra as prophylaxis to prevent or reduce the frequency of bleeding episodes (not acute treatment).
- The beneficiary has documentation of any previous treatment with episodic and prophylactic bypassing agents (FEIBA, NovoSeven RT, or Sevenfact)
- The beneficiary has documentation of ONE of the following:
  - The beneficiary had an inadequate response to immune tolerance induction (ITI); **OR**
  - Rationale for why the beneficiary is not a candidate for ITI.
- Provider attestation that beneficiary will NOT be receiving concurrent prophylactic treatment with bypassing agents or has possibility of receiving ITI while taking Hemlibra.
- Initial prior authorization (PA) will be for 1 month for the FDA-approved loading dose of 3 mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis.

APPROVAL CONSIDERATION FOR HEMOPHILIA A WITHOUT INHIBITORS:

- The beneficiary has a documented diagnosis of congenital hemophilia A **without** inhibitors and **with** ONE of the following:
  - Severe disease with < 1% of factor VIII in blood while on factor VIII products.
  - Moderate disease with 1-5% of factor VIII in blood while on factor VIII products with ONE of the following:
    - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; **OR**
    - At least two joint bleeds causing hemophilia-related joint damage; **OR**
    - Poor venous access; **OR**
    - High factor VIII dose.
- Hemlibra is prescribed by or in consultation with a hematologist or hemophilia specialist.

- The beneficiary has documentation for use of Hemlibra as prophylaxis to prevent or reduce the frequency of bleeding episodes (not acute treatment).
- The provider attests that the beneficiary will NOT be receiving concurrent prophylaxis factor VIII.
- Initial prior authorization (PA) will be for 1 month for the FDA-approved loading dose of 3 mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis.

EXCLUSIONS

- The beneficiary does not have a diagnosis of congenital hemophilia A.
- The beneficiary continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents).
- The beneficiary is not compliant on their prescribed Hemlibra dose.
- The beneficiary has no positive therapeutic response with the decrease of bleeding episodes or decreased episodic agent use.

APPROVAL DURATION

Refer to **Initial Approval Considerations** above

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that the beneficiary has experienced a therapeutic response from Hemlibra as defined by either:
  - Reduced frequency of bleeds; **OR**
  - Reduced severity of bleeds

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7170 – Injection, emicuzumab-kxwh, 0.5 mg

HEMOPHILIA PRODUCTS – FACTOR VIII (AFSTYLA, ELOCTATE)

Updated: 11/08/2022

INDICATIONS

Indicated for treatment of **hemophilia A (congenital factor VIII deficiency) in adults and children**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of congenital factor VIII deficiency
- The product is not used for the treatment of von Willebrand disease
- The product is used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage)
  - Perioperative management (Authorizations are valid for 1 month)
  - Routine prophylaxis
    - Used to prevent or reduce the frequency of bleeding episodes
      - The beneficiary must have severe hemophilia A (factor VIII level of < 1%); **OR**
      - The beneficiary has at least two documented episodes of spontaneous bleeding into joints

APPROVAL DURATION

- May be renewed
- Approval is for 6 months for on-demand treatment and control of bleeding episodes AND for routine prophylaxis.
- **Note**: Lengthy approval periods, (e.g., 6 months) for use in perioperative management do not meet medical necessity. Therefore, approval duration is limited to 1 month when the product is used for perioperative management.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the product (e.g., symptoms of allergic-anaphylactic reactions, thromboembolic events, development of neutralizing antibodies, etc.)
- The beneficiary has demonstrated a beneficial response to therapy (e.g., the frequency of bleeding episodes has decreased from pre-treatment baseline)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7205 – Eloctate, 1IU = 1 billable unit equivalent
- J7210 – Afstyla, 1IU = 1 billable unit equivalent

HERCEPTIN (TRASTUZUMAB), KANJINTI (TRASTUZUMAB-ANNS)

Updated: 10/20/2023

INDICATIONS

Trastuzumab and Trastuzumab-anns are indicated for treatment of:

- **HER2-overexpressing breast cancer**
- **HER2-overexpressing metastatic gastric cancer or gastroesophageal junction adenocarcinoma**

CLINICAL CRITERIA

- The beneficiary is 18 years or older.
- Baseline left ventricular ejection fraction (LVEF) is within normal limits.
- The beneficiary's cancer is human epidermal growth factor receptor 2 (HER2)-positive

Adjuvant breast cancer

- Trastuzumab is indicated for adjuvant treatment of HER2-overexpressing node positive or node negative breast cancer:
  - As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - As part of a treatment regimen with docetaxel and carboplatin
  - As a single agent following multi-modality anthracycline-based therapy

Neoadjuvant breast cancer

- Trastuzumab is indicated for use in combination with pertuzumab (Perjeta) and chemotherapy as neoadjuvant treatment in beneficiaries with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either > 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.

Metastatic breast cancer

- Trastuzumab is indicated:
  - In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
  - As a single agent for treatment of HER2-overexpressing breast cancer in beneficiaries who have received one or more chemotherapy regimens for metastatic disease

Metastatic gastric cancer

- Trastuzumab is indicated, in combination with cisplatin and either capecitabine or 5-fluorouracil, for the treatment of beneficiaries with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.

APPROVAL DURATION

- Trastuzumab is approved for 6 months of treatment of early breast cancer that is HER2-positive:
  - With lymph node involvement; **OR**

- **Without** lymph node spread and **with** one of the following:
  - Tumor size > 2 cm; **OR**
  - Tumor grade 2 or 3
- Trastuzumab is approved for 6 months of treatment of metastatic breast cancer that is HER2-positive

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., cardiotoxicity, including left ventricular dysfunction or cardiomyopathy, pulmonary toxicity [pneumonitis], neutropenia, infusion-related reactions, etc.)
- Left ventricular ejection fraction (LVEF) has not had an absolute decrease of more than 15% from baseline and remains with normal limits.

BILLING/CODING INFORMATION

- J9355 – Injection, trastuzumab, 10 mg; 1 billable unit = 10 mg
- Q5117 – Injection, trastuzumab-anns, biosimilar, (kanjinti) 10 mg

HYALURONIC ACID DERIVATIVES

Updated: 01/23/2025

INDICATIONS

FDA-approved indication:

- **Hyaluronic acid derivatives are indicated for the treatment of pain in osteoarthritis (OA) of the knee in beneficiaries who have failed to respond adequately to conservative non-pharmacologic therapy, simple analgesics (e.g., acetaminophen), NSAIDs, tramadol, or intraarticular steroid injections**

CLINICAL CRITERIA

- The beneficiary must be 18 years of age or older
- The beneficiary must have documented symptomatic osteoarthritis of the knee
- The medication must be prescribed by an orthopedic surgeon, interventional pain physicians, rheumatologists, physiatrists (PM&R) and all sports medicine subspecialties
- Documentation that the beneficiary has tried and failed ALL of the following:
  - Attempts at weight loss or at lifestyle modifications to promote weight loss (only for beneficiaries with BMI $\geq$30
  - Sufficient trial (e.g., 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical/occupational therapy)
  - At least 3 simple analgesic therapies (acetaminophen, NSAIDs, oral or topical salicylates)
- The beneficiary is not using the hyaluronic acid derivative medication for hip or shoulder related conditions.
- The beneficiary has no contraindications to the injections (e.g., active joint infection, bleeding disorder)

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- A medical record demonstrating a reduction in the dose of NSAIDs (or other analgesics or anti-inflammatory medication) during the 6-month period following the previous series of injections
- A medical record objectively documenting significant improvement in pain and functional capacity as the result of the previous injections/
- Absence of unacceptable toxicity from the previous injections.
  - Example of unacceptable toxicity include:
    - Severe joint swelling and pain
    - Severe infections
    - Anaphylactic or anaphylactoid reactions

BILLING/CODING INFORMATION

Applicable Procedure Codes					
HCPCS Code	**Billing Unit**	**Drug Name**	**Dosing frequency per series (per knee)**	**Dose (per knee)**	**Units per dose (per knee)**
J7321	per dose	Hyalgan	3 to 5 weekly injections	20 mg once weekly	1 unit
J7321	per dose	Supartz	3 to 5 weekly injections	25 mg once weekly	1 unit
J7321	per dose	Visco-3	3 weekly injections	25 mg once weekly	1 unit
J7323	per dose	Euflexxa	3 weekly injections	20 mg once weekly	1 unit
J7324	per dose	Orthovisc	3 to 4 weekly injections	30 mg once weekly	1 unit
J7326	per dose	Gel-One	Single injection	30 mg x 1 dose	1 unit
J7327	per dose	Monovisc	Single injection	88 mg x 1 dose	1 unit
J7328	per 0.1 mg	Gelsyn-3	3 weekly injections	16.8 mg once weekly	168 units
J7329	per 1 mg	TriVisc	3 weekly injections	25 mg once weekly	25 units
J7318	per 1 mg	Durolane	Single Injection	60 mg x 1 dose	60 units
J7320	per 1 mg	Genvisc 850	3 to 5 weekly injections	25 mg once weekly	25 units
J7325	per 1 mg	Synvisc	3 weekly injections	16 mg once weekly	16 units
J7325	per 1 mg	Synvisc-One	Single injection	48 mg x 1 dose	48 units
J7322	per 1 mg	Hymovis	2 weekly injections	24 mg once weekly	24 units
J7331	per 1 mg	Synojoynt	3 weekly injections	20 mg once weekly	20 units

HYCAMTIN (TOPOTECAN)

Updated: 03/17/2025

INDICATIONS

Hycamtin is indicated for treatment of:

- **Ovarian cancer**
- **Small cell lung cancer (SCLC)**
- **Cervical cancer**

CLINICAL CRITERIA

Ovarian cancer

- The beneficiary has a diagnosis of ovarian cancer (including epithelial, primary peritoneal, and fallopian tube cancers)
- The beneficiary is ≥ 18 years of age
- The drug is prescribed by or in consultation with an oncologist
- The beneficiary has experienced disease progression on or after initial or subsequent chemotherapy
- The drug is used a as a single agent; **OR**
- The drug is used in combination with bevacizumab3 or sorafenib4 (off-label)

Small cell lung cancer

- The beneficiary has a diagnosis of small cell lung cancer
- The beneficiary is ≥ 18 years of age
- The drug is prescribed by or in consultation with an oncologist
- The beneficiary has received prior chemotherapy
- The drug is used as a single agent

Cervical cancer

- The beneficiary has a diagnosis of stage IV-B cervical cancer
- The beneficiary is ≥ 18 years of age
- The drug is prescribed by or in consultation with an oncologist
- The drug is used in combination with cisplatin or paclitaxel

NCCN RECOMMENDED USES

Ewing sarcoma and osteosarcoma (bone cancer)

- The drug is used as a second line therapy in combination with cyclophosphamide

Leptomeningeal metastases (CNS cancers)

- Intrathecal injection

Non-pleomorphic rhabdomyosarcoma (soft tissue carcinoma)

- The drug is used as a single agent or in combination with cyclophosphamide

Endometrial carcinoma (uterine neoplasms)

- The drug is used as a single agent

Merkel cell carcinoma

- The beneficiary has a contraindication to checkpoint immunotherapy (e.g., avelumab, pembrolizumab, nivolumab)

OTHER RECOMMENDED USES

High-risk neuroblastoma (pediatric)

- The drug is used as a single agent; **OR**
- The drug is used in combination with I-metaiodobenzylguanidine (I-MIBG)

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has positive disease response, as indicated by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., myelosuppression [neutropenia, thrombocytopenia, anemia], interstitial lung disease, extravasation and tissue injury, etc.)

DOSAGE AND ADMINISTRATION

- **Ovarian cancer and small cell lung cancer**
  - 1.5 mg/m^2 by intravenous infusion over 30 minutes daily for 5 consecutive days, starting on day 1 of a 21-day cycle
- **Cervical cancer**
  - 0.75 mg/m^2 by intravenous infusion over 30 minutes on days 1, 2, and 3, with cisplatin 50 mg/m^2 on day 1, of a 21-day cycle

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9351 – Injection, topotecan, 0.1 mg; 1 billable unit = 0.1 mg

HYQVIA SCIG (SUBCUTANEOUS IMMUNOGLOBULIN)

Updated: 03/17/2025

INDICATIONS

- **Primary immunodeficiency (PI) in adults and pediatric beneficiaries.**
  - Primary immunodeficiency includes:
    - Common variable immunodeficiency (CVID)
    - X-linked agammaglobulinemia
    - Congenital agammaglobulinemia
    - Wiskott-Aldrich Syndrome
- **Chronic inflammatory demyelinating polyneuropathy (CIDP)**

CLINICAL CRITERIA

PRIMARY IMMUNODEFICIENCY (PI)

- The beneficiary is 2 years of age or older.
- The beneficiary has baseline values for BUN and serum creatinine obtained within 30 days of request.
- The beneficiary's IgG level is < 200 mg/dL, **OR both** of the following:
  - The beneficiary 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 or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The beneficiary 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
- Beneficiary has tried and failed to tolerate intravenous immunoglobulin (IVIG) therapy

INITIAL IVIG CONSIDERATIONS USED FOR DETERMINATION OF COVERAGE (REFERENCE USE ONLY)

- The beneficiary's disease course is progressive or relapsing and remitting for two months or longer; **AND**
- The beneficiary has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least two motor nerves; **OR**
    - Partial motor conduction block in one nerve plus one other demyelination criterion listed here in at least one other nerve; **OR**

  - Distal CMAP duration increase in at least one nerve plus one other demyelination criterion listed here in at least one other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least two motor nerves; **OR**
  - Reduced conduction velocity in at least two motor nerves; **OR**
  - Prolonged distal motor latency in at least two motor nerves; **OR**
  - Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least one other nerve; **OR**
  - Prolonged F wave latency in at least two motor nerves; **AND**
- Cerebrospinal fluid analysis indicates the following:
  - CSF white cell count of <10 cell/mm^3; **AND**
  - CSF protein is elevated; **AND**
- The beneficiary 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.)

CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

Used as maintenance therapy in adults 18 years of age or older.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug.
- BUN and serum creatinine obtained within the last 6 months, and the concentration and rate of infusion have been adjusted accordingly.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1575 – Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg = 1 billable unit

ILUMYA (TILDRAKIZUMAB-ASMN)

Updated: 03/15/2024

INDICATIONS

Plaque Psoriasis

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The drug is prescribed by or in consultation with a dermatologist.
- The beneficiary has a documented diagnosis of chronic moderate to severe plaque psoriasis with at least one of the following:
  - ≥ 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis.
  - The beneficiary has tried at least one traditional systemic agent (e.g., methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for psoriasis for at least 3 months, unless intolerant; **AND**
  - Documented history of failure to one of the following therapies unless contraindicated or clinically significant adverse effects are experienced:
    - Anthralin
    - Coal tar preparations
    - Corticosteroids
    - Immunomodulators (e.g., Cimzia, Otezla, Skyrizi, Stellara, Tremfya, Enbrel)
    - Vitamin D analogues
    - Tazarotene
    - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
    - Retinoic acid derivatives

DOSAGE AND ADMINISTRATION

Subcutaneous injection 100 mg/mL at week 0 and 4, then 100 mg every 12 weeks thereafter.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that the beneficiary experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, or scale of areas affected by psoriasis; **AND**
- Compared to baseline, the beneficiary experienced an improvement in at least one symptom, such as decreased pain, itching, or burning.

- The beneficiary is not receiving Ilumya in combination with another targeted immunomodulator (e.g., Enbrel, Cimzia, Simponi, Orencia, Stelara, Skyrizi, Tremfya, Cosentyx, Taltz, Siliq, Xeljanz, Rinvoq, Otezla)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3245 − Injection, tildrakizumab, 1 mg: 1 billable unit = 1 mg

ILUVIEN (FLUOCINONIDE ACETONIDE IMPLANT)

Updated: 03/17/2025

INDICATIONS

Iluvien is indicated for treatment of:

- **Diabetic macular edema (DME)**
- **Chronic non-infectious uveitis**

CLINICAL CRITERIA

Diabetic macular edema (DME)

- The beneficiary has been treated with a course of corticosteroids
- The beneficiary did not have a clinically significant rise in intraocular pressure from prior corticosteroid treatment
- The beneficiary is free of intraocular infections
- The beneficiary does not have glaucoma with a cup to disk ratio greater than 0.8

Chronic non-infectious uveitis

- The beneficiary has chronic non-infectious uveitis affecting the posterior eye segment

APPROVAL DURATION

Approval is for 1 implant per eye and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline
- Absence of unacceptable toxicity from the drug (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, eye inflammation, posterior subcapsular cataracts, glaucoma, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7313 − Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg; 1 billable unit = 0.01 mg

IMDELLTRA (TARLATAMAB-DLLE)

Updated: 11/22/2024

INDICATIONS

Imdelltra is indicated for the treatment of adult beneficiaries with **extensive-stage small cell lung cancer (ES-SCLC)** with disease progression on or after platinum-based chemotherapy.

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has relapsed or refractory extensive-stage small cell lung cancer.
- The beneficiary has previously received platinum-based chemotherapy.
- The beneficiary has documented Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1.
- Imdelltra is prescribed by or in consultation with an oncologist.
- **Note**: Imdelltra carries an FDA **Black Box Warning** for cytokine release syndrome (CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

The beneficiary should be closely monitored for signs and symptoms of cytokine release syndrome (CRS), neurotoxicity and immune effector cell-associated neurotoxicity syndrome (ICANS) during treatment.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documented disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe cytopenia, severe infection, severe hepatotoxicity, severe hypersensitivity, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3490 – Unclassified drugs
- C9170 – Injection, tarlatamab-dlle, 1 mg; 1 billable unit = 1 mg (Effective 10/01/2024)

IMFINZI (DURVALUMAB)

Updated: 08/11/2025

INDICATIONS

Imfinzi is indicated for:

- **Non-small cell lung cancer (NSCLC)**
- **Extensive-stage small cell lung cancer (ES-SCLC)**
- **Limited-stage (early-stage) small-cell lung cancer**
- **Biliary tract cancer (BTC)**
- **Hepatocellular carcinoma (uHCC)**
- **Primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR)**
- **Muscle invasive bladder cancer (MIBC)**
- **Gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)**

CLINICAL CRITERIA

- The beneficiary must be at least 18 years of age.
- The beneficiary has not experienced disease progression while on previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., atezolizumab, avelumab, durvalumab, nivolumab, etc.)

Non-small cell lung cancer (NSCLC):

- The drug is used in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, for the treatment of adult beneficiaries with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
- The drug is used as a single agent for the treatment of adult beneficiaries with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- The drug is used in combination with tremelimumab-actl (IMJUDO) and platinum-based chemotherapy for the treatment of adult beneficiaries with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations

Extensive-stage small cell lung cancer (ES-SCLC):

- The drug is used in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult beneficiaries with extensive-stage small cell lung cancer (ES-SCLC).

Limited-stage small cell lung cancer (LS-SCLC)

- The drug is used as a single agent for the treatment of adult beneficiaries with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Biliary tract cancer (BTC)

- The drug is used in combination with gemcitabine and cisplatin for treatment of adult beneficiaries with locally advanced or metastatic biliary tract cancer (BTC)

Hepatocellular carcinoma (uHCC)

- The drug is used in combination with tremelimumab-actl (IMJUDO) for treatment of adult beneficiaries with unresectable hepatocellular carcinoma (uHCC).

Primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR)

- The drug is used in combination with carboplatin and paclitaxel, followed by INFINZI as a single agent, for the treatment of adult beneficiaries with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

Bladder cancer (MIBC)

- In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent durvalumab (Imfinzi) as adjuvant treatment following radical cystectomy, for treatment of adults with muscle invasive bladder cancer (MIBC).

Gastric or gastroesophageal junction adenocarcinoma

- In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent durvalumab (Imfinzi) as adjuvant treatment following radical cystectomy, for treatment of adult beneficiaries with muscle invasive bladder cancer (MIBC).

APPROVAL DURATION

Coverage will be for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., immune-mediated adverse reactions, such as hepatitis, colitis, endocrinopathies, nephritis, severe infections, severe infusion-related reactions, etc.)

BILLING/CODING INFORMATION

Applicable service codes:

J9173 – Injection, durvalumab, 10 mg; 1 billable unit = 10 mg

IMJUDO (TREMELIMUMAB-ACTL)

Updated: 03/20/2025

INDICATIONS

Imjudo is indicated for treatment of:

- **Hepatocellular carcinoma (uHCC)**
- **Non-small cell lung cancer (NSCLC)**

CLINICAL CRITERIA

Hepatocellular carcinoma (uHCC)

- The beneficiary is 18 years of age or older.
- The beneficiary has unresectable disease.
- Imjudo is used as first-line systemic therapy.
- Imjudo is used in combination with durvalumab (Imfinzi) intravenous infusion.
- Imjudo is prescribed by or in consultation with an oncologist.

Non-small cell lung cancer (NSCLC)

- The beneficiary is 18 years of age or older.
- The beneficiary has metastatic disease.
- The tumor is negative for epidermal growth factor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- Imjudo is used as first-line systemic therapy.
- Imjudo is used in combination with durvalumab (Imfinzi) and platinum-based chemotherapy.

APPROVAL DURATION

Hepatocellular carcinoma

- Approval is for one dose only and may not be renewed.

Non-small cell lung cancer

- Approval is provided for five doses only and may not be renewed.

RENEWAL/REAUTHORIZATION

May not be renewed.

DOSAGE AND ADMINISTRATION

The recommended dose of Imjudo is weight-based. For beneficiaries with hepatocellular carcinoma, the recommended dose is as follows:

- For beneficiaries ≥ 30 kg: Imjudo 300 mg as a single intravenous (IV) dose administered in combination with Imfinzi 1,500 mg IV on day 1 of cycle 1. Imfinzi is then continued as a single agent once every 4 weeks until disease progression or unacceptable adverse events.

- For beneficiaries < 30 kg: Imjudo 4 mg/kg as a single IV dose administered in combination with Imfinzi 20 mg/kg IV on day 1 of cycle 1. Imfinzi is then continued as a single agent once every 4 weeks until disease progression or unacceptable adverse events.

The recommended dose for NSCLC is as follows:

- For beneficiaries ≥ 30 kg: Imjudo 75 mg IV administered once every 3 weeks in combination with Imfinzi 1,500 mg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 1,500 mg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 75 mg IV is administered with Imfinzi dose 6 at week 16. Imfinzi is continued until disease progression or unacceptable adverse events.
- For beneficiaries < 30 kg: Imjudo 1 mg/kg IV administered once every 3 weeks in combination with Imfinzi 20 mg/kg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 20 mg/kg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 1 mg/kg IV is administered with Imfinzi dose 6 at week 16. Imfinzi is continued until disease progression or unacceptable adverse events.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- C9147 – Injection, tremelimumab-actl, 1 mg; 1 billable unit = 1 mg

IMLYGIC (TALIMOGENE LAHERPAREPVEC)

Updated: 03/20/2025

INDICATIONS

Imlygic is indicated for local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in beneficiaries with **melanoma** recurrent after initial surgery.

- The beneficiary has a diagnosis of unresectable metastatic (stage IIIB/C–IVM1a) melanoma.

LIMITATIONS OF USE

Per FDA, Imlygic has not been shown to improve overall survival or have an effect on visceral metastases.

COMPENDIAL USES

- Limited resectable or unresectable stage III melanoma with clinical satellite/in-transit metastases
- Unresectable distant metastatic melanoma (extracranial lesions)
- Limited resectable or unresectable local satellite/in-transit recurrence of melanoma
- Unresectable or incomplete resection of nodal occurrence in beneficiaries with melanoma

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Continued injectable lesions to treat
- Disease response with treatment as described by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity (e.g., herpetic infection, injection site complications such as necrosis, ulceration, cellulitis, or systemic bacterial infection, immune-mediated events, plasmacytoma at injection site, obstructive airway disorder, etc.)

DOSAGE AND ADMINISTRATION

- Imlygic is available in 106 (1 million) plaque-forming units (PFU) per mL, and 108 (100 million) PFU per mL for injection, in single-use vials (1 mL).
- The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment.
- Per FDA labeling, previously injected or uninjected lesions may be injected at subsequent treatment visits. The initial recommended dose is up to 4 mL of Imlygic at a concentration of 106 (1 million) PFU per mL. The recommended dose for subsequent administrations is up to 4 mL of Imlygic at a concentration of 108 (100 million) PFU per mL.

EXPERIMENTAL AND INVESTIGATIONAL

Imlygic in combination with other immune therapies (e.g., Yervoy [ipilimumab], Keytruda [pembrolizumab], Opdivo [nivolumab], etc.,) are experimental and investigational for the treatment of melanoma and other cancers.

Imlygic is experimental and investigational for the treatment of the following indications because its effectiveness for these indications has not been established:

- Merkel cell carcinoma
- Neuroendocrine cancer
- Non-melanoma skin cancers
- Solid tumors (e.g., bladder, brain including glioblastoma, breast, colon, head and neck, kidney, liver, lung, mesothelioma, ovary, pancreas, prostate, and sarcoma).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9325 - Injection, talimogene laherparepvec, per 1 million plaque forming units; 1 billable unit = 106 (1 million) PFU

INFLIXIMAB (REMICADE, INFLECTRA, RENFLEXIS, AVSOLA)

Updated: 03/20/2025

INDICATIONS

FDA APPROVED INDICATIONS

Remicade is indicated for:

- **Crohn's disease**
- **Pediatric Crohn's disease**
- **Ulcerative colitis**
- **Pediatric ulcerative colitis**
- **Rheumatoid arthritis**
- **Ankylosing spondylitis**
- **Psoriatic arthritis**
- **Plaque psoriasis**

OTHER APPROVED INDICATIONS

- **Hidradenitis suppurativa**
- **Juvenile dermatomyositis and polymyositis**
- **Juvenile idiopathic arthritis**
- **Neurologic sarcoidosis (neurosarcoidosis)**
- **Pyoderma gangrenosum**
- **Uveitis**

CLINICAL CRITERIA

Universal inclusions

- The beneficiary has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment.
- The beneficiary has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment.
- The beneficiary does not have an active infection, including clinically important significant localized infections.
- The drug must not be administered concurrently with live vaccines or therapeutic infectious agents (e.g., BCG bladder instillation for bladder cancer, etc.)
- The beneficiary is not receiving concurrent treatment with another TNF inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, baricitinib)

Crohn's disease

- The drug must be prescribed by or in consultation with a specialist in gastroenterology
- The drug is used for inducing and maintaining clinical remission in adults with moderate to severe disease.

- The drug is used for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult beneficiaries with fistulizing disease.

Pediatric Crohn's disease

- The beneficiary is at least 6 years of age
- The drug must be prescribed by or in consultation with a specialist in gastroenterology
- The physician has documented that the beneficiary has moderate to severe disease

Ulcerative colitis

- The drug must be prescribed by or in consultation with a specialist in gastroenterology
- The physician has documented that the beneficiary has moderate to severe disease

Pediatric ulcerative colitis

- The beneficiary is at least 6 years of age
- The drug must be prescribed by or in consultation with a specialist in gastroenterology
- The physician has documented that the beneficiary has moderate to severe disease

Rheumatoid arthritis (RA)

- The drug must be prescribed by or in consultation with a specialist in rheumatology
- The physician has documented that the beneficiary has moderate to severe disease
- The beneficiary has had at least a 3-month trial and failed previous therapy with ONE oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide)
- The drug is used in combination with methotrexate, unless contraindicated

Psoriatic arthritis

- The drug must be prescribed by or in consultation with a specialist in dermatology or rheumatology
- The physician has documented that the beneficiary has moderate to severe active disease:
  - For beneficiaries with both of the following:
    - Predominantly axial disease OR active enthesitis or dactylitis; **AND**
    - Trial and failure of at least TWO non-steroidal anti-inflammatory agents (NSAIDS), unless contraindicated.
  - For beneficiaries with peripheral arthritis, a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine)

Ankylosing spondylitis

- The drug must be prescribed by or in consultation with a specialist in rheumatology
- The physician has documented that the beneficiary has active disease
- The beneficiary has had a trial and failure of at least TWO non-steroidal anti-inflammatory agents (NSAIDS), unless use is contraindicated

Plaque psoriasis

- The drug must be prescribed by or in consultation with a dermatologist or rheumatologist

- The physician has documented that the beneficiary has had moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA)
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater
  - Incapacitation or serious emotional consequences due to plaque location (e.g., head and neck, palms, soles of feet or genitalia) or with intractable pruritis
- The beneficiary did not respond adequately to (or is not a candidate for) a minimum 3-month trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressive agents, keratolytic agents, retinoic acid derivatives, or vitamin D analogues)
- The beneficiary did not respond adequately to (or is not a candidate for) a minimum 3-month trial of at least one systemic agent (e.g., immunosuppressive agent, retinoic acid derivatives, or methotrexate)
- The beneficiary did not respond adequately to (or is not a candidate for) a minimum 3-month trial of phototherapy (e.g., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

Juvenile dermatomyositis and polymyositis

- The beneficiary is 2 years of age or older
- The drug is prescribed by a specialist in rheumatology
- The beneficiary has active dermatomyositis or polymyositis disease
- The physician has assessed baseline disease severity utilizing an objective measure/tool

Juvenile idiopathic arthritis (JIA)

- The beneficiary is 2 years of age or older
- The drug is prescribed by a specialist in rheumatology
- The beneficiary has active systemic (SJIA) or polyarticular (PJIA) disease
- The physician has assessed baseline disease severity utilizing an objective measure/tool
- The beneficiary has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) **OR** a systemic glucocorticoid (prednisone, methylprednisolone, etc.)
- May be used alone or in combination with methotrexate

Neurologic sarcoidosis (neurosarcoidosis)

- The drug is prescribed by or in consultation with a specialist familiar in treating this disease

Pyoderma gangrenosum

- The drug is prescribed by or in consultation with a specialist in dermatology
- The beneficiary has tried at least one systemic corticosteroid (e.g., prednisone); **OR**
  - The beneficiary has tried an immunosuppressant (e.g., mycophenolate mofetil, cyclosporine, etc.) for at least 2 months or was intolerant to one of these agents

Uveitis

- The drug is prescribed by or in consultation with a specialist in ophthalmology or rheumatology

APPROVAL DURATION

- Authorization is for 6 months and may be renewed
- **Note**: Beneficiaries who do not respond by week 14 are unlikely to respond with continued dosing, and consideration should be given to discontinue Infliximab in these beneficiaries.

RENEWAL/REAUTHORIZATION

Recommended renewal based upon the following:

- The beneficiary continues to meet the criteria for initial approval and relevant guidelines
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, malignancy significant hematologic abnormalities, serious infections, cerebrovascular accidents, cardiotoxicity or heart failure, neurotoxicity, hepatotoxicity, lupus-like syndrome, demyelinating disease, etc.)
- The beneficiary is monitored for presence of TB; however, repeat latent TB infection testing should be focused on beneficiaries who have new risk factors for TB infection since their last screening.

Crohn's disease

- 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, or an improvement on a disease activity scoring tool (e.g. an improvement on the Crohn's Disease Activity Index [CDAI] score or the Harvey-Bradshaw Index score).

Pediatric Crohn's disease

- 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, or an improvement on a disease activity scoring tool (e.g. an improvement on the Crohn's Disease Activity Index [CDAI] score or the Harvey-Bradshaw Index score)

Ulcerative colitis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as stool frequency, rectal bleeding, or endoscopic activity, tapering or discontinuation of corticosteroid therapy, or an improvement on a disease activity scoring tool (e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity [UCEIS] score or the Mayo Score)

Pediatric ulcerative colitis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as stool frequency, rectal bleeding, or endoscopic activity, tapering or discontinuation of corticosteroid therapy, or an improvement on a disease activity scoring tool (e.g. an improvement on the Pediatric Ulcerative Colitis Activity Index [PUCAI] score or the Mayo Score)

Rheumatoid arthritis (RA)

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of

beneficiary global assessment, or an improvement on a disease activity scoring tool (e.g. an improvement on a composite scoring index such as Disease Activity Score-28 [DAS28] of 1.2 points or more or a ≥ 20% improvement on the American College of Rheumatology-20 [ACR20] criteria)

Psoriatic arthritis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as the number of tender and swollen joint counts or an improvement on a disease activity scoring tool (e.g., defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria [PsARC], 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria).

Ankylosing spondylitis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as total back pain, physical function, morning stiffness, or an improvement on a disease activity scoring tool (e.g., ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score [ASDAS] or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]).

Plaque psoriasis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as redness, thickness, scaliness, the amount of surface area involvement (total BSA involvement ≤ 1%), or an improvement on a disease activity scoring tool (e.g., a 75% reduction in the PASI score from when treatment started [PASI 75] or a 50% reduction in the PASI score [PASI 50] and a four-point reduction in the DLQI from when treatment started).

Juvenile dermatomyositis and polymyositis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline.

Juvenile idiopathic arthritis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as the number of tender and swollen joint counts or an improvement on a disease activity scoring tool (e.g., an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score [JADAS] or the American College of Rheumatology [ACR] Pediatric [ACR-Pedi 30] of at least 30% improvement from baseline in three of six variables).

Uveitis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as reduction in inflammation or lesions, dose reduction of oral glucocorticoids or immunosuppressive agents, improvement in vitreous haze, improvement in best corrected visual acuity, disease stability, or reduced rate or decline.

Pyoderma gandrenosum

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, as documented by the prescribing physician.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1745 – Injection, infliximab, excludes biosimilar, 10 mg, 1 billable unit = 10 mg
- Q5103 – Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg: 1 billable unit = 10 mg
- Q5104 – Injection, infliximab-abda, biosimilar, (renflexis), 10 mg; 1 billable unit = 10 mg
- Q5121 – Injection, infliximab-axxq, biosimilar, (avsola), 10 mg: 1 billable unit=10 mg

IVIG (INTRAVENOUS IMMUNOGLOBULIN) – BIVIGAM, CARIMUNE NF, FLEBOGAMMA, GAMMAGARD, GAMMAGARD S/D, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

Updated: 03/12/2025

INDICATIONS

Intravenous immune globulins are FDA approved for the following indications:

- **Adult dermatomyositis (DM)**
- **Chronic inflammatory demyelinating polyneuropathy (CIDP)**
- **Immune thrombocytopenia / idiopathic thrombocytopenic purpura (ITP)**
- **Multifocal motor neuropathy (MMN)**
  - FDA-approved indication for Gammagard. Also listed as recommended indication under Compendial use.
- **Primary immunodeficiency (PID) / Wiskott-Aldrich syndrome in adult and pediatric beneficiaries** (e.g., x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) (**list not all inclusive**)
- **Primary (inherited) immunodeficiency (PI)**

CLINICAL CRITERIA

Primary immunodeficiency/Wiskott-Aldrich syndrome

- The beneficiary's IgG level is < 200 **OR both** of the following
  - The beneficiary 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 pneumonia within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections, including septicemia

Immune thrombocytopenia/idiopathic thrombocytopenia purpura (ITP)

- For acute disease state:
  - Used to manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30 x 10^9/L)
  - Used to increase platelet counts prior to invasive surgical procedures (e.g., splenectomy)
  - The beneficiary has severe thrombocytopenia (platelet counts less than 20 x 10^9/L) and is considered to be at risk for intracerebral hemorrhage

- For chronic immune thrombocytopenia (CIT)
  - The beneficiary is at increased risk for bleeding as indicated by a platelet count less than 30 x 10^9/L
  - The beneficiary has a documented history of failure, contraindication, or intolerance to corticosteroids
  - Duration of illness > 6 months
  - The beneficiary is ≥ 2 years of age

Chronic inflammatory demyelinating polyneuropathy (CIDP)

- The beneficiary's disease course is progressive or relapsing and remitting for 2 months or longer
- The beneficiary has abnormal or absent deep tendon reflexes in upper or lower limbs
- The beneficiary has received electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least two 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 listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves
  - Reduced conduction velocity in at least 2 motor nerves
  - Prolonged distal motor latency in at least 2 motor nerves
  - Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
  - Prolonged F wave latency in at least 2 motor nerves
- Cerebrospinal fluid (CSF) analysis indicates the following:
  - CSF white cell count < 10 cells/mm^3; **AND**
  - CSF protein is elevated
- The beneficiary is refractory to or intolerant of corticosteroids (e.g., prednisolone, prednisone) given in therapeutic doses over at least three months

Multifocal motor neuropathy (MMN)

- Maintenance therapy to improve muscle strength and disability in adult beneficiaries with multifocal motor neuropathy.

PANS/PANDA COVERAGE

Ark. Code Ann. § 23-79-1905(f) requires a health benefit plan that is offered, issued, or renewed in Arkansas to provide coverage for the use of intravenous immunoglobulin to treat individuals diagnosed with Pediatric Acute-onset Neuropsychiatric Syndrome (PANS) and Pediatric Acute-onset Neuropsychiatric Disorders Associated with Streptococcus (PANDAS), or both, on or after January 1, 2024, if the pediatric beneficiary's primary care physician, in consultation with an Arkansas licensed pediatric psychiatrist and an Arkansas licensed physician who practices in at least one pediatric subspecialty, including a neurologist, rheumatologist, or infectious disease physician who has treated the pediatric beneficiary determines and agrees that the treatment is necessary and follows a beneficiary-specific treatment plan.

- Only after a consultation and recommendation is issued by a pediatric subspecialist (e.g., pediatric neurologist, pediatric immunologist, pediatric rheumatologist, or pediatric infectious disease specialist) for IVIG treatment, then:
  - Up to 3 monthly immunomodulatory courses of IVIG therapy may be approved for treatment of PANDAS and PANS.
  - A reevaluation at 3 months by the pediatric sub-specialist will be required for continued therapy of IVIG. This evaluation must include objective clinical testing by a specialist trained in structured or semi-structured interview assessments, such as a neuropsychologist, which must be performed both pre-treatment and post-treatment to demonstrate significant clinical improvement.

COMPENDIAL USES FOR INTRAVENOUS IMMUNOGLOBULINS (IVIG) – LISTED ALPHABETICALLY

- Acquired red cell aplasia
- Acute disseminated encephalomyelitis
- Autoimmune mucocutaneous blistering diseases
- Autoimmune hemolytic anemia
- Autoimmune neutropenia
- Birdshot retinochoroidopathy
- BK virus associated nephropathy
- Bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT)
- Churg-Strauss syndrome
- Enteroviral meningoencephalitis
- Fetal/neonatal alloimmune thrombocytopenia
- Guillain-Barré syndrome
- Hematophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
- Hemolytic disease of newborn
- Human immunodeficiency virus (HIV) infection – prophylaxis of bacterial infections in pediatric beneficiaries
- HIV-associated thrombocytopenia
- Hyperimmunoglobulinemia E syndrome
- Hypogammaglobulinemia from chimeric antigen receptor T (CAR-T) therapy
- Immune checkpoint inhibitor-related toxicities management
- Juvenile dermatomysositis (recurrent or refractory to first-line treatment)
- Kawasaki disease (adult and pediatric)
- Lambert-Eaton myasthenic syndrome
- Measles (rubeola) prophylaxis
- Multifocal motor neuropathy
- Multiple myeloma
- Myasthenia gravis
- Neonatal hemochromatosis, prophylaxis
- Opsoclonus-myoclonus

- Paraneoplastic opsonus-myoclonus ataxia associated with neuroblastoma
- Parvovirus B19-induced pure red cell aplasia
- Polymyositis
- Post-transfusion purpura
- Rasmussen encephalitis
- Renal transplantation from a live donor with ABO incompatibility or positive cross match
- Secondary immunosuppression associated with major surgery, hematological malignancy, major burns, and collagen-vascular diseases
- Scleroderma
- Solid organ transplantation, for allosensitized members
- Stiff-person syndrome
- Systemic lupus erythematosus (SLE)
- Tetanus treatment and prophylaxis
- Toxic epidermal necrolysis and Stevens-Johnson syndrome
- Toxic shock syndrome
- Toxic necrotizing fasciitis due to group A streptococcus
- Varicella prophylaxis

APPROVAL DURATION

Approval for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Continued therapy is considered medically necessary when the beneficiary is responding to therapy (e.g., there is a stability or improvement in symptoms, significant improvement in disability and maintenance of improvement have occurred since initiation of IVIG, etc.).

BILLING/CODING INFORMATION

Applicable Procedure Codes:

J-Codes:

Drug	Manufacturer	J-Code
Bivigam	Biotest Pharmaceuticals	J1556
Carimune NF	CSL Behring AG	J1556
Flebogamma	Instituto Grifols, S.A.	J1572
Gamunex-C	Talecris Biotherapeutics	J1561
Gammagard	Baxter Healthcare Corporation	J1569
Gammagard S/D	Baxter Healthcare Corporation	J1566
Gammaked	Talecris Biotherapeutics	J1561
Gammaplex	Bio Products Laboratory	J1557
Octagam	Octapharma USA, Inc.	J1568

Drug	Manufacturer	J-Code
Panzyga	Octapharma USA, Inc	J1576
Privigen	CSL Behring AG	J1459
Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified	N/A	J1599

IV/INJECTABLE IRON PRODUCTS – INJECTAFER (FERRIC CARBOXYMALTOSE), MONOFERRIC (FERRIC DERISOMALTOSE), VENOFER (IRON SUCROSE INJECTION)

Updated: 03/20/2025

INDICATIONS

INJECTAFER (FERRIC CARBOXYMALTOSE)

Injectafer is an iron replacement product indicated for the treatment of:

- Adult and pediatric beneficiaries 1 year of age or older who have either an intolerance to oral iron or an unsatisfactory response to oral iron.
- Adult beneficiaries who have non-dialysis-dependent chronic kidney disease (CKD).
- Iron deficiency in adult beneficiaries with heart failure and New York Heart Association class II/III to improve exercise capacity.

Other approved indications:

- Cancer and chemotherapy-induced anemia

Note: Prior authorization is NOT required for Injectafer when the beneficiary is 18 years of age or older

- The beneficiary must be less than 18 years of age.
- The beneficiary has iron-deficiency anemia with a Hemoglobin (Hb) < 12 g/dL
  - Ferritin ≤100 ng/mL; **OR**
  - Ferritin ≤ 300 ng/mL when transferrin saturation (TSAT) ≤ 20%

MONOFERRIC (FERRIC DERISOMALTOSE)

Monoferric is an iron replacement product indicated for the treatment of iron deficiency anemia in adult beneficiaries who have:

- Intolerance to oral iron or an unsatisfactory response to oral iron.
- Non-hemodialysis-dependent chronic kidney disease.
  - The beneficiary is at least 18 years of age.
  - Other causes of anemia (e.g., blood loss, vitamin deficiency, etc.) have been ruled out.
  - Use of monoferric product is allowable during pregnancy.

VENOFER (IRON SUCROSE INJECTION)

Venofer is indicated for treatment of iron deficiency anemia in the following adults and pediatric beneficiaries (2 years of age and older) with chronic kidney disease:

- Beneficiaries with non-dialysis-dependent chronic kidney disease beneficiaries who are receiving an erythropoietin.
- Beneficiaries with non-dialysis-dependent chronic kidney disease beneficiaries who are not receiving an erythropoietin.
- Beneficiaries with hemodialysis-dependent chronic kidney disease beneficiaries who are receiving an erythropoietin.

- Beneficiaries with peritoneal dialysis-dependent chronic kidney disease beneficiaries who are receiving an erythropoietin.

Additional prescribing indications:

- Beneficiaries needing iron supplementation who are unable to tolerate compounds given orally or for whom oral iron is not effective
- Beneficiaries who are losing iron (blood) at a rate too rapid for oral intake to compensate for the loss
- Beneficiaries with a disorder of the gastrointestinal tract, such as inflammatory bowel disease (ulcerative colitis and Crohn's disease), in which symptoms may be aggravated by oral iron therapy
- Beneficiaries who are donating large amounts of blood for autologous programs
- Beneficiaries with iron deficiency and chemotherapy-induced anemia
- Beneficiaries with heart failure and iron deficiency with or without anemia
- Beneficiary with iron deficiency anemia due to heavy uterine bleeding
- Beneficiary with iron deficiency following gastric bypass surgery or subtotal gastric resection and who exhibited decreased absorption of oral iron

CONTRAINDICATIONS

- Intravenous iron therapy is contraindicated and considered experimental and investigational for those with genetic hemochromatosis or hemochromatosis secondary to iron overload.
- Intravenous iron therapy is contraindicated and considered experimental and investigational for all other indications, including the following, because its clinical value for these indications has not been established:
  - Acute mountain sickness
  - Anemia of inflammation
  - Anemia of pregnancy that does not meet the above indications.
    - **Note**: IV iron is not given during the first trimester but can be started after 13 weeks
  - Post-partum anemia
  - Prophylactic use to improve function in non-anemic beneficiaries undergoing orthopedic surgery (e.g., hip fracture)
  - Prophylactic use to prevent postoperative anemia in beneficiaries undergoing bariatric surgery.
  - Restless leg syndrome
  - Treatment of post-operative anemia following major surgery (e.g., cardiothoracic surgery, colorectal cancer surgery, and neurosurgery)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Same as prescribing indications

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1437 – Injection, ferric derisomaltose, 10 mg
- J1439 – Injection, ferric carboxymaltose, 1 mg
- J1756 – Injection, iron sucrose, 1 mg

IXEMPRA (IXABEPILONE)

Updated: 03/20/2025

INDICATIONS

Ixempra is indicated for treatment of:

- **Breast Cancer**
  - In combination with capecitabine for beneficiaries with metastatic or locally advanced breast cancer that is resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated
  - As a single agent for beneficiaries with metastatic or locally advanced breast cancer after failure of an anthracycline, a taxane, and capecitabine.

CLINICAL CRITERIA

Per FDA warning: Ixempra in combination with capecitabine is contraindicated in beneficiaries with AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN due to increased risk of toxicity and neutropenia-related death.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., peripheral neuropathy, myelosuppression [neutropenia, leukopenia, anemia, and thrombocytopenia], hepatic impairment, hypersensitivity reactions, cardiac ischemia, impaired cardiac function, etc.)

BILLING/CODING INFORMATION

J9207 – Injection, ixabepilone, 1mg; 1 billable unit = 1mg

IZERVAY (AVACINCAPTAD PEGOL INTRAVITREAL SOLUTION)

Updated: 08/11/2025

INDICATIONS

Izervay is indicated for the treatment of

- **Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**

CLINICAL CRITERIA

- Documented diagnosis of geographic atrophy secondary to age-related degeneration.
- Absence of choroidal neovascularization (CNV or wet AMD) in the treatment eye.
- Normal luminance best corrected visual acuity (BCVA) ≥ 24 letters (20/320 Snellen equivalence)
- Total GA lesion area ≥ 2.5 and ≤ 17.5 mm^2, with at least 1 lesion ≥ 1.25 mm^2 if GA is multifocal
- Presence of any pattern of hyperautofluorescence in the junctional zone of GA
- The beneficiary is ≥ 50 years of age
- Izervay is prescribed by an ophthalmologist
- Requested dosing is 2 mg (0.1 mL) every 28 days

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease response with treatment, and the beneficiary does not show evidence of progressive disease while on therapy.
- The beneficiary has not developed nAMD (wet AMD).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2782 - Injection, avacincaptad pegol, 0.1 mg

JEMPERLI (DOSTARLIMAB-GXLY)

Updated: 08/02/2024

INDICATIONS

Jemperli is indicated for treatment of:

- **Endometrial cancer (EC)**
- **Mismatch repair deficit (dMMR) recurrent or advanced solid tumors**

CLINICAL CRITERIA

- Jemperli is prescribed by an oncologist.

Endometrial cancer (EC)

- Used in combination with carboplatin and paclitaxel, followed by Jemperli, as a single agent for the treatment of adult beneficiaries with primary advanced or recurrent endometrial cancer.
- Used as a single agent for the treatment of adult beneficiaries with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum containing regimen in any setting and for which the beneficiary is not a candidate for curative surgery or radiation.

Mismatch repair deficient recurrent or advanced solid tumors

- Used as a single agent for the treatment of adult beneficiaries with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment in beneficiaries who have no satisfactory alternative treatment options.

NCCN RECOMMENDATIONS

Rectal cancer

- Used as a single agent for neoadjuvant/definitive treatment of dMMR/MSI-H rectal cancer if the beneficiary has not received previous treatment with a checkpoint inhibitor, for up to 6 months only

APPROVAL DURATION

Approval is for 6 months and may be renewed, unless otherwise noted (e.g., NCCN recommendation for rectal cancer is limited to 6 months only, no renewal).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, severe immune-mediated adverse reactions [e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, dermatologic adverse reactions, etc.], complication of allogeneic HSCT after immunotherapy)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9272 – Injection, dostarlimab-gxly, 10 mg; 1 billable unit = 10mg

JEVTANA (CABAZITAXEL)

Updated: 03/20/2025

INDICATIONS

Jevtana is indicated for use in combination with prednisone for treatment of beneficiaries with metastatic castration-resistant prostate cancer that was previously treated with a docetaxel-containing treatment regimen.

- **Prostate cancer**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- Must be used in combination with a steroid (e.g., prednisone or dexamethasone)
- The beneficiary has castration-resistant metastatic disease.
- The beneficiary must have been previously treated with a docetaxel-containing regimen.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as defined by lack of disease progression, improvement in tumor size, or improvement in beneficiary symptoms.
- Absence of unacceptable toxicity from the drug (e.g., neutropenia, anemia, leukopenia, thrombocytopenia, severe hypersensitivity reactions, severe diarrhea, nausea, vomiting, severe hemorrhagic cystitis, renal or hepatic toxicity, intestinal lung disorders, etc).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9043 – Injection, cabazitaxel, 1 mg; 1 billable unit = 1 mg

KADCYLA (ADO-TRASTUZUMAB EMTANSINE)

Updated: 03/25/2025

INDICATIONS

Kadcyla is indicated for treatment of:

- **HER-2 positive breast cancer**

CLINICAL CRITERIA

- For the treatment of beneficiaries with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. The beneficiary should either:
  - Have received prior therapy for metastatic disease; **OR**
  - Have developed disease recurrence during or within six months of completion of adjuvant therapy; **OR**
- For the adjuvant treatment of beneficiaries with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor
- Kadcyla has several boxed warnings, including hepatotoxicity, liver failure, reductions in left ventricular ejection fraction (LVEF), embryo-fetal toxicity, and death. Hepatic function and LVEF should be assessed prior to initiation of Kadcyla and monitored regularly for need to modify or withhold dosage or discontinue as appropriate.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9354 - Injection, ado-trastuzumab emtansine, 1 mg; 1 billable unit = 1 mg

KEYTRUDA (PEMBROLIZUMAB), KEYTRUDA QLEX (PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH)

Updated: 10/02/2025

INDICATIONS

Keytruda and Keytruda Qlex are indicated for the following, **except as noted**:

- **Melanoma**
- **Non-small cell lung cancer (NSCLC)**
- **Malignant pleural mesothelioma (MPM)**
- **Head and neck squamous cell carcinoma (HNSCC)**
- **Small cell lung cancer (SCLC)**
- **Classical Hodgkin lymphoma (cHL)**
  - **Note**: Not indicated for Keytruda Qlex
- **Primary mediastinal large B-cell lymphoma (PMBCL)**
  - **Note**: Not indicated for Keytruda Qlex
- **Urothelial carcinoma**
- **Microsatellite instability-high (MSI-H) cancer**
- **Microsatellite instability-high or mismatch repair deficient colorectal cancer (CRC)**
- **Gastric cancer**
- **Esophageal cancer**
- **Cervical cancer**
- **Hepatocellular cancer (HCC)**
- **Biliary tract cancer (BTC)**
- **Merkel cell carcinoma (MCC)**
- **Renal cell carcinoma (RCC)**
- **Endometrial carcinoma**
- **Tumor mutational burden-high (TMB-H) cancer**
  - **Note**: The most common TMB-H cancers are small cell lung cancer, cervical cancer, endometrial cancer, anal cancer, and vulvar cancer. However, Keytruda is approved for treating some types of lung, head and neck, stomach, liver, kidney, bladder, and skin cancers, as well as some types of lymphoma.
- **Cutaneous squamous cell carcinoma (cSCC)**
- **Triple negative breast cancer (TNBC)**

CLINICAL CRITERIA

Melanoma

- The beneficiary's disease is unresectable or metastatic.
- For the adjuvant treatment of adult and pediatric (12 years of age or older) beneficiaries with Stage IIB, IIC, or III melanoma following complete resection.

Non-small cell lung cancer (NSCLC) ¥

- In combination with pemetrexed and platinum chemotherapy as first-line treatment of beneficiaries with metastatic **non-squamous NSCLC** with no EGFR or ALK genomic tumor aberrations
- In combination with carboplatin and either paclitaxel or paclitaxel protein-bound as first-line treatment of beneficiaries with metastatic **squamous NSCLC**.
- As a single agent for the first-line treatment of beneficiaries with NSCLC expressing PD-L1 (Tumor Proportion Score [TPS] ≥ 1%), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, that is either:
  - Stage III and the beneficiary is not a candidate for surgical resection or definitive chemoradiation; **OR**
  - Metastatic
- As a single agent for the treatment of beneficiaries with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%), as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Beneficiaries with EGFR or ALK genomic tumor aberrations should have disease progression on an FDA-approved therapy for these aberrations prior to receiving Keytruda; **OR**
- For the treatment of beneficiaries with resectable (tumors ≥ 4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery; **OR**
- As a single agent for adjuvant treatment following resection and platinum-based chemotherapy for adult beneficiaries with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC; **OR**
- Used as continuation maintenance therapy for beneficiaries who achieved tumor response or stable disease following initial therapy when Keytruda was used in combination with pemetrexed and either carboplatin or cisplatin for disease of non-squamous cell histology **OR**
- Used as continuation maintenance therapy for beneficiaries who achieved tumor response or stable disease following initial therapy when Keytruda was used as first-line treatment in combination with carboplatin and paclitaxel for disease of squamous cell histology.
- **¥ NCCN Guidelines Version 1.2024 Non-Small Cell Lung Cancer recommendations**
  - **When molecular testing results are pending:**
    - For beneficiaries who require an urgent start to therapy but molecular testing is pending, consider holding immunotherapy for one cycle, unless there is confirmation that no driver mutations are present.
  - **When specimen for biopsy was insufficient and re-biopsy or plasma testing is not deemed appropriate by the treating physician:**
    - Treatment is guided by available results, and, if unknown, these beneficiaries are treated as though they do not have driver oncogenes.

Malignant pleural mesothelioma (MPM)

- Used in combination with pemetrexed and platinum chemotherapy as first-line treatment of adult beneficiaries with unresectable advanced or metastatic MPM

Head and neck squamous cell cancer (HNSCC)

- Used in combination with platinum and FU for the first-line treatment of beneficiaries with metastatic or with unresectable, recurrent HNSCC

- Used as a single agent for the first-line treatment of beneficiaries with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1) as determined by an FDA-approved test
- Used as a single agent for the treatment of beneficiaries with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy
- For beneficiaries with resectable, locally-advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 1), used as a single agent for neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin after surgery, and then as a single agent.

Small cell lung cancer (SCLC)

- For treatment of beneficiaries with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy

Classical Hodgkin lymphoma (cHL)

- For the treatment of adult beneficiaries with relapsed or refractory cHL
- For the treatment of pediatric beneficiaries with relapsed cHL or cHL that has relapsed after 2 or more lines of therapy

Primary mediastinal large B-cell lymphoma (PMBCL)

- The beneficiary has relapsed or refractory disease
- The beneficiary must be at least 2 years of age
- Used after two or more prior lines of therapy

Urothelial carcinoma

- Used in combination with enfortumab vedotin-ejfv (Padcev) for the treatment of adult beneficiaries with locally advanced or metastatic urothelial cancer
- Used as a single agent for the treatment of beneficiaries with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy **OR** beneficiaries who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Used as a single agent for the treatment of beneficiaries with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors for which the beneficiary is ineligible for or has elected not to undergo cystectomy

Microsatellite instability-high (MSI-H) or mismatch repair deficient cancer

- Used for the treatment of adult and pediatric beneficiaries with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior treatment in beneficiaries who have no satisfactory alternative treatment options, **OR** colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Microsatellite instability-high or mismatch repair deficient colorectal cancer (CRC)

- Used for the first-line treatment of beneficiaries with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC)

Gastric cancer

- Used in combination with trastuzumab-, fluoropyrimidine-, and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced, unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥1); **OR**
- Used in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally-advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma

Esophageal cancer

- Used for the treatment of beneficiaries with recurrent, locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:
  - In combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
  - As a single agent after one or more prior lines of systemic therapy for beneficiaries with tumors of squamous cell histology that express PD-L1 (Combined Positive Score [CPS] ≥ 10)

Cervical cancer

- Used in combination with chemoradiotherapy for the treatment of beneficiaries with Federation of Gynecology and Obstetrics (FIGO) 2014 Stage III-IVA cervical cancer.
- Used in combination with chemotherapy, with or without bevacizumab, for the treatment of beneficiaries with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS) ≥ 1; **OR**
- Used as a single agent for the treatment of recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS) ≥ 1 with disease progression on or after chemotherapy.

Hepatocellular carcinoma (HCC)

- For the treatment of HCC secondary to hepatitis B in beneficiaries who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen

Biliary tract cancer (BTC)

- Used in combination with gemcitabine and cisplatin for the treatment of beneficiaries with locally advanced, unresectable or metastatic biliary tract cancer.

Merkel cell carcinoma

- **The beneficiary must meet all of the following:**
  - For treatment of adult and pediatric beneficiaries with recurrent, locally advanced or metastatic Merkel cell carcinoma

Renal cell carcinoma

- Used in combination with Inlyta (axitinib) for the first-line treatment of adult beneficiaries with advanced RCC
- Used in combination with lenvatinib for first-line treatment of adult beneficiaries with advanced RCC
- For the adjuvant treatment of beneficiaries with RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

- **Note**: The definition of intermediate-high or high risk of recurrence is tumor stage 2 with nuclear grade 4 or sarcomatoid differentiation, tumor stage 3 or higher, regional lymph-node metastasis, or stage M1 with no evidence of disease.

Endometrial cancer

- Used in combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult beneficiaries with primary advanced or recurrent endometrial carcinoma.
- Used in combination with lenvatinib for the treatment of beneficiaries with advanced endometrial carcinoma that is not MSI-H or dMMR in beneficiaries who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation; **OR**
  - Used as a single agent for the treatment of beneficiaries with advanced endometrial carcinoma that is MSI-H or dMMR in beneficiaries who have disease progression following prior systematic therapy in any setting and who are not candidates for curative surgery or radiation

Tumor mutational burden-high (TMB-H) cancer

- Used for the treatment of adult and pediatric beneficiaries with unresectable or metastatic tumor mutational burden-high (TMB-H) (≥ 10 mutations/megabase [mut/MB]) solid tumors that have progressed following prior treatment in beneficiaries who have no satisfactory alternative treatment options

Cutaneous squamous cell carcinoma (cSCC)

- Used for the treatment of beneficiaries with recurrent or metastatic cSCC or locally advanced cSCC that is not curable by surgery or radiation

Triple negative breast cancer (TNBC)

- Used for the treatment of beneficiaries with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery. (**Note**: TNBC is defined as newly diagnosed, previously untreated, nonmetastatic disease [tumor stage T1c, nodal stage N1-2, or tumor stage T2-4, nodal stage N0-2].)
- The drug can be used in combination with chemotherapy for the treatment of beneficiaries with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (Combined Positive Score [CPS] >10).
- Per NCCN guidelines, the drug can be used with carboplatin/paclitaxel followed by cyclophosphamide plus either doxorubicin or epirubicin.
- Triple Negative Breast Cancer is defined as PR-/HER2-/ER < 1%. Clinical studies are underway for “ER-Low” breast cancer with PR-/HER2-/1% < ER < 10%. Off-label use of pembrolizumab for ER-low breast cancer may be appropriate with careful consideration.

NCCN RECOMMENDATIONS

Cutaneous melanoma

- Used for neoadjuvant therapy of Stage III cutaneous melanoma

Pediatric diffuse high-grade gliomas

- Used as adjuvant treatment for hypermutant tumor pediatric diffuse high-grade glioma or for recurrent or progressive disease

Rectal cancer

- Used as a single agent for neoadjuvant/definitive treatment of dMMR/MSI-H rectal cancer if the beneficiary has not received previous treatment with a checkpoint inhibitor. Approval is for up to 6 months only.

Vulvar cancer

- Used in combination with chemotherapy as first-line treatment of advanced or recurrent/metastatic disease.
- May be continued as monotherapy maintenance.

APPROVAL DURATION

Approval is for 6 months and may be renewed, unless otherwise noted (e.g., NCCN recommendation for rectal cancer is limited to 6 months only, no renewal).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., hepatic toxicity, grade 2 or greater: pneumonitis, colitis, endocrinopathies, nephritis, etc.)
- For **melanoma (metastatic or unresectable disease):**
  - The beneficiary has ECOG performance status score of 0, 1, or 2.
  - The drug is used as re-induction therapy in beneficiaries who experienced disease control with subsequent disease progression/relapse > 3 months after treatment discontinuation.
- For **non-small cell lung cancer (NSCLC):**
  - The beneficiary's disease has not progressed during treatment with Keytruda.
  - The beneficiary has not experienced unacceptable toxicity (e.g., hepatic toxicity, grade 2 or greater: pneumonitis, colitis, endocrinopathies, nephritis, etc.)

BILLING/CODING INFORMATION

Applicable service codes:

- J9271 - Injection, pembrolizumab, 1 mg; 1 billable unit = 1 mg

KORSUVA (DIFELIKEFALIN)

Updated: 06/21/2024

INDICATIONS

Korsuva is indicated for the treatment of moderate-to-severe pruritis associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis.

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has a documented diagnosis of chronic kidney disease.
- The beneficiary has been receiving hemodialysis at least three times weekly for at least three months (Korsuva is not indicated for pruritis associated with peritoneal dialysis).
- The beneficiary has documented moderate-to-severe pruritis.
- Pruritis is not attributed to a cause other than end stage renal disease or its complications (e.g., pruritic dermatological disease, cholestatic liver disease).
- The beneficiary has had a trial of and inadequate response to one other pruritis therapy (e.g., topical agents, glucocorticoids, gabapentin, or pregabalin).
- The beneficiary has a documented baseline score from an objective clinical evaluation tool (e.g., Worst Itching Intensity Numerical Rating Scale [WI-NRS], etc.)
- Korsuva is prescribed by or in consultation with a nephrologist.

APPROVAL DURATION

Approval is for 3 months initially to evaluate response to therapy, then approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe dizziness, somnolence, mental status changes, gait disturbances, etc.
- Documentation of positive clinical response to therapy, as demonstrated by clinically significant improvement or stabilization in pruritis from baseline.
- The beneficiary will continue to receive hemodialysis at least three times weekly.
- The beneficiary has received optimal dialysis treatment in the last three months, defined as one of the following on different dialysis days:
  - Two single-pool Kt/V measurements $\geq$ 1.2
  - Two urea reduction ratio measurements $\geq$ 65%
  - One pool Kt/V measurement $\geq$ 1.2 and one urea reduction ratio measurement $\geq$ 65%

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0879 – Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis); 1 billable unit = 0.1 mcg.

KRYSTEXXA (PEGLOTICASE)

Updated: 03/25/2025

INDICATIONS

Krystexxa is indicated for treatment of:

- **Chronic gout**

CLINICAL CRITERIA

- Treatment of adult beneficiaries diagnosed with chronic gout that is refractory to conventional therapy
- The beneficiary has one of the following:
  - At least 3 gout flares in the previous 18 months that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), or oral or injectable corticosteroids; **OR**
  - At least 1 gout tophus or chronic gouty arthritis
- The beneficiary has documentation of baseline serum uric acid level > 8 mg/dL (current lab reports are required for renewal)
- Per FDA, beneficiaries at high risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency should be screened and found negative for G6PD before starting Krystexxa.

LIMITATIONS OF USE

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

APPROVAL DURATION

Authorization is for six months and is eligible for renewal.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment (e.g., reduction of symptoms, reduction of tophi)
- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis, infusion reactions, exacerbation of congestive heart failure)
- Documentation of serum uric acid level < 6 mg/dL prior to scheduled infusion

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2507 – Injection, pegloticase, 1 mg; 1 billable unit = 1 mg

KYMRIAH (TISAGENLECLEUCEL)

Updated: 11/01/2024

INDICATIONS

Kymriah is indicated:

- **B-cell precursor acute lymphoblastic leukemia (ALL)**
- **Relapsed or refractory large B-cell lymphoma**
- **Relapsed or refractory follicular lymphoma**

CLINICAL CRITERIA

Initial guidelines for approval:

- The beneficiary does not have an active infection or inflammatory disorder
- The beneficiary has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment
- The beneficiary has been 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)
- The beneficiary has not received prior CAR-T therapy
- The drug is used as a single agent therapy (not applicable to lymphodepleting or bridging chemotherapy)
- The beneficiary has a life expectancy > 12 weeks

Disease-specific guidelines for approval in addition to the above:

- For treatment of beneficiaries ≤ 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, defined as one of the following:
  - Second or greater bone marrow relapse; **OR**
  - Any bone marrow relapse after allogeneic stem cell transplantation (SCT); **OR**
  - Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy) or chemo-refractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease); **OR**
  - Beneficiaries with Philadelphia chromosome (Ph)-positive disease have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib, ponatinib, etc.); **OR**
  - The beneficiary is not eligible for allogenic SCT
- For treatment of adult beneficiaries with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma and DLBCL arising from follicular lymphoma.
- For treatment of adult beneficiaries with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

EXCLUSIONS

- Isolated extramedullary relapse

- Concomitant genetic syndromes associated with bone marrow failure states (e.g., Fanconi anemia, Kostmann syndrome, Schwachman syndrome, or any other bone marrow failure syndrome, with the exception of Down Syndrome)
- Burkitt's lymphoma/leukemia
- Active or latent hepatitis B or active hepatitis C, or any uncontrolled infection
- Grade 2 to 4 graft versus host Disease (GVHD)
- Active CNS involvement by malignancy

APPROVAL DURATION

Authorization will be provided for one treatment course (1 dose of Kymriah) and may not be renewed

RENEWAL/REAUTHORIZATION

Authorization cannot be renewed

BILLING/CODING INFORMATION

Applicable service codes:

- Q2042 – Tisagenlecleucel, up to 600 million car-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose

KYPROLIS (CARFILZOMIB)

Updated: 03/25/2025

INDICATIONS

Kyprolis is indicated for treatment of:

- **Relapsed/refractory multiple myeloma**

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age
- The drug must be prescribed by an oncologist or hematologist

Multiple myeloma

- The beneficiary has received one to three lines of therapy in combination with:
  - Lenalidomide and dexamethasone; **OR**
  - Dexamethasone; **OR**
  - Daratumumab and dexamethasone; **OR**
  - Daratumumab and hyaluronidase-fihj (Darzalex Faspro) and dexamethasone; **OR**
  - Isatuximab (Sarclisa) and dexamethasone
- Used as a single agent for the treatment of beneficiaries with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Stabilization of disease or absence of progression of disease
- Absence of unacceptable toxicity from the drug (e.g., cardiac events [heart failure and ischemia], pulmonary toxicity, pulmonary hypertension, dyspnea, infusion reactions, tumor lysis syndrome, thrombocytopenia, hepatic toxicity/failure, thrombotic microangiopathy [TTP/HUS], acute renal failure, severe hypertension, posterior reversible encephalopathy syndrome [PRES], etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9047 – Injection, carfilzomib, 1 mg; 1mg = 1 billable unit

LANREOTIDE (SOMATULINE DEPOT, LANREOTIDE ACETATE) INJECTION

Updated: 03/25/2025

INDICATIONS

Somatuline Depot is indicated for treatment of:

- **Acromegaly**
- **Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**
- **Carcinoid syndrome**

CLINICAL CRITERIA

FDA PRESCRIBING INDICATIONS

Acromegaly

- The beneficiary has a diagnosis of acromegaly.
- The drug is prescribed by or in consultation with an endocrinologist or oncologist.
- The beneficiary is an adult at least 18 years of age.
- The beneficiary has documented inadequate response to surgery or radiotherapy or it is not an option for the beneficiary.
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal requires reporting of current levels).
- The drug will not be used in combination with oral octreotide.

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

- The drug is prescribed by or in consultation with an endocrinologist or oncologist.
- The drug is used to treat adult beneficiaries with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to inhibit growth of tumors, improve progression-free survival, and provide symptom relief.

Carcinoid syndrome

- The beneficiary has documented neuroendocrine tumors with a history of carcinoid syndrome (flushing or diarrhea).
- The drug is prescribed by or in consultation with an endocrinologist or oncologist.
- The drug is used to reduce the frequency of short-acting somatostatin analog rescue therapy, for treatment or control of symptoms, and to inhibit growth of tumors.

COMPENDIA APPROVED INDICATIONS

- **Neuroendocrine and adrenal tumors (e.g., GI tract, lung, thymus, pancreas, and pheochromocytoma/paraganglioma)**
- **Pancreatic neuroendocrine tumor**
  - Used to manage symptoms related to hormone hypersecretion of locoregional neuroendocrine tumors of the pancreas (well differentiated grade 1/2).
    - The beneficiary has a diagnosis of gastrinoma, glucagonoma, or VIPoma.

- Used for tumor control of locoregional advanced or distant metastatic neuroendocrine tumors of the pancreas (well differentiated grade 1/2 – gastrinoma, glucagonoma, insulinoma, VIPoma).

- **Pheochromocytoma or paraganglioma**
  - The beneficiary has symptomatic, locally resectable, somatostatin receptor-positive disease or distant metastatic disease.
- **Not indication specific**
  - The beneficiary has unresectable, locally advanced or metastatic neuroendocrine tumors (well differentiated grade 3).

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., formation of gallstones, cardiovascular abnormalities [bradycardia, sinus bradycardia, and hypertension], uncontrolled blood glucose abnormalities [hyperglycemia or hypoglycemia], thyroid disorders [hypothyroidism], etc.)
- **Acromegaly:**
  - Disease response, as indicated by an improvement in signs and symptoms compared to baseline:
    - Reduction of growth hormone
    - Age-adjusted normalization of serum IGF-1
- **Gastroenteropancreatic neuroendocrine tumors (GEP-NETs):**
  - Disease response with treatment, as indicated by an improvement in symptoms, including reduction in symptomatic episodes (e.g., diarrhea, rapid gastric dumping, flushing, bleeding, etc.), stabilization of glucose levels, or decrease in tumor size or tumor spread.
- **Carcinoid syndrome:**
  - Disease response with treatment, as indicated by reduction in use of short-acting somatostatin analog rescue medication (e.g., octreotide), an improvement in symptoms, including reduction in symptomatic episodes (such as diarrhea, flushing), or decrease in tumor size or tumor spread.
- **Neuroendocrine and adrenal tumors:**
  - Disease response with treatment as indicated by an improvement in symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) or stabilization of glucose levels or decrease in tumor size or tumor spread.
  - The beneficiary has had disease progression, and therapy will be continued in beneficiaries with functional tumors.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1930 – Injection, lanreotide, 1 mg (Somatuline Depot); 1 billable unit = 1 mg
- J1932 – Injection, lanreoide, 1 mg (cipla), 1 billable unit = 1 mg

LARTRUVO (OLARATUMAB)

Updated: 03/25/2025

INDICATIONS

Soft tissue sarcoma

- Lartruvo is used in combination with doxorubicin for the treatment of adult beneficiaries with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

CLINICAL CRITERIA

- The drug is prescribed by an oncologist.
- The beneficiary is an adult 18 years of age or older.
- The drug is used in combination with doxorubicin when an anthracycline containing regimen is appropriate.
  - The drug is used for one of the following histologic subtypes of disease:
    - Angiosarcoma
    - Pleomorphic rhabdomyosarcoma
    - Retroperitoneal/intra-abdominal sarcoma
    - Extremity/superficial trunk/head-neck sarcoma
      - Primary treatment as chemotherapy or chemoradiation for stage II-III resectable disease with adverse functional outcomes
    - Uterine sarcoma
      - May be considered following total hysterectomy with or without bilateral salpingo-oophorectomy for Stage I-III disease
- The disease is not amenable to curative radiotherapy or surgery

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, mucositis, lymphopenia, neutropenia, thrombocytopenia, etc.).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9285 – Injection, olaratumab, 10 mg; 1 billable unit = 10 mg
- J9999 – Not otherwise classified, antineoplastic drugs
- C9485 – Injection, olaratumab; 10 mg; 1 billable unit = 10 mg

LEMTRADA, CAMPATH (ALEMTUZUMAB)

Updated: 09/09/2024

INDICATIONS

Lemtrada is indicated for treatment of:

- **Relapsing forms of multiple sclerosis**

Campath is approved for the treatment of:

- **B-cell chronic lymphocytic leukemia (B-CLL)**
  - Campath is generally administered at higher and more frequent doses than recommended in the treatment of multiple sclerosis.
  - Providers requesting authorization for Campath must indicate use is for B-cell chronic lymphocytic leukemia (B-CLL)

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has received a baseline skin exam for melanoma.
- The beneficiary will not receive live vaccines following a course of Lemtrada or Campath.
- The beneficiary has been diagnosed with a relapsing form of multiple sclerosis (e.g., relapsing-remitting disease [RRMS] or secondary progressive MS [SPMS] with relapses)
- The drug is used as a single agent therapy.
- Per FDA prescribing guidelines and because of its safety profile, the use of Lemtrada should generally be reserved for beneficiaries who have had an inadequate response to two or more drugs indicated for the treatment of MS.

OFF-LABEL USES

Aplastic anemia, refractory (off-label use): Campath, *Per UpToDate (09/09/2024)*

CONTRAINDICATIONS

- Concomitant use of Lemtrada and Campath
  - Lemtrada (alemtuzumab) is the same drug as Campath. Beneficiaries must not receive both drugs simultaneously.
- Not recommended for use in beneficiaries with first clinical episode of multiple sclerosis (MS) that displays characteristics of inflammatory demyelination that may be MS but have not yet met the diagnostic criteria of MS.
- Not recommended for beneficiaries with human immunodeficiency virus (HIV) infection.

DOSING RECOMMENDATIONS

- **Relapsing forms of multiple sclerosis:**
  - Administer by intravenous infusion over 4 hours for 2 treatment courses:
    - First course: 12 mg/day on 5 consecutive days
    - Second course: 12 mg/day on 3 consecutive days 12 months after first treatment course

- Subsequent treatment courses of 12 mg per day on 3 consecutive days may be administered, as needed, at least 12 months after the last dose of any prior treatment course.

- **B-cell chronic lymphocytic leukemia (B-CLL)**
  - Administer as an IV infusion over 2 hours (not as IV push or bolus)
  - Gradually escalate to the maximum recommended single dose of 30 mg
  - Maintenance dose: 30 mg per day, 3 times per week on alternate days
  - Total duration of therapy, including dose escalation, is 12 weeks.

RENEWAL/REAUTHORIZATION

May not be renewed or reauthorized.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0202 - Injection, alemtuzumab, 1 mg (1mg = 1 billable unit)

LENMELDY (ATIDARSAGENE AUTOTEMCEL)

Updated: 06/26/2025

INDICATIONS

Lenmeldy (atidarsagene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

Treatment consists of a single intravenous infusion of Lenmeldy consisting of autologous CD34+ cells, containing hematopoietic stem cells (HSCs) transduced with a lentiviral vector (LVV) encoding the human arylsulfatase A (ARSA) gene and suspended in cryopreservation solution. Mobilization, apheresis, and myeloablative conditioning are required prior to Lenmeldy infusion. Myeloablative conditioning is performed to remove the native HSPCs that carry the defective ARSA gene.

After Lenmeldy infusion, transduced HSPCs engraft in bone marrow, repopulate the hematopoietic compartment, and their progeny produce the ARSA enzyme. This functional ARSA enzyme assists in breaking down and preventing the harmful accumulation of sulfatides. Dosing of Lenmeldy is based on the number of CD34+ cells in the infusion bags per kg of body weight. Minimum recommended dose is based on the MLD disease subtype.

CLINICAL CRITERIA

- Lenmeldy is prescribed by or in consultation with a prescriber specializing in the treatment of MLD (i.e., neurologist or pediatric neurologist).
- The beneficiary 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).
- The beneficiary has not received other gene therapy for MLD.
- The beneficiary has documentation of an arylsulfatase A (ARSA) genotype (biallelic ARSA pathogenic variant); **AND**
  - Biochemical testing of deficient ARSA enzyme activity in leukocytes (ARSA activity below the normal range in peripheral blood mononuclear cells or fibroblasts); **AND**
  - Elevated urinary sulfatide levels
- The beneficiary has one of the following forms of MLD:
  - Presymptomatic late infantile (PSLI) with expected disease onset at or before 30 months of age and an ARSA genotype consistent with LI MLD; **OR**
  - Presymptomatic early juvenile (PSEJ) MLD with expected disease onset > 30 months and < 7 years of age and an ARSA genotype consistent with EJ MLD; **OR**
  - Early symptomatic early juvenile (ESEJ) disease with disease onset > 30 months of age and < 7 years of age and an ARSA genotype consistent with EJ MLD.

APPROVAL DURATION

Lenmeldy is given as a **one-time dose (once per lifetime)** by IV infusion.

DOSING LIMITS

- Lenmeldy is given as a **one-time dose (once per lifetime)** by IV infusion.
  - A single dose of Lenmeldy contains 2 to 11.8 x 10^6 cells/mL (1.8 to 11.8 x 10^6 CD34+ cells/mL) suspended in one or more beneficiary-specific infusion bags.
- Dosing of Lenmeldy is based on the number of CD34+ cells in the infusion bags per kg of body weight.
  - Presymptomatic late infantile: IV infusion: Minimum dose: 4.2 x 10^6 CD34+ cells/kg as a single dose; maximum dose: 30 x 10^6 CD34+ cells/kg.
  - Presymptomatic early juvenile: IV infusion: Minimum dose: 9 x 10^6 CD34+ cells/kg as a single dose; maximum dose: 30 x 10^6 CD34+ cells/kg.
  - Early symptomatic early juvenile: IV infusion: Minimum dose: 6.6 x 10^6 CD34+ cells/kg as a single dose; maximum dose: 30 x 10^6 CD34+ cells/kg.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3391 – Injection, Atidarsagene Autotemcel, per treatment

LEQEMBI (LECANEMAB-IRMB)

Updated: 09/17/2025

INDICATIONS

Leqembi is indicated for treatment of:

- **Alzheimer's disease (AD)**
  - Treatment with Leqembi should be initiated in beneficiaries with diagnosed new onset, progressive Alzheimer's with mild cognitive impairment (MCI) or mild dementia stage of disease after proper informed consent of the risks and benefits of the treatment.

CLINICAL CRITERIA

- The beneficiary is ≥ 50 years of age.
- The physician has assessed baseline disease severity utilizing at least ONE objective measure/tool, including:
  - Clinical Dementia Rating-Sum of Boxes (CDR-SB)
  - Mini-Mental Status Exam (MMSE)
  - Montreal Cognitive Assessment (MoCA)

Note: The above cognitive tests are the most commonly used but do not represent an exhaustive list. Use of alternative cognitive assessment tests not listed will be reviewed on a case-by-case basis.

- Leqembi is prescribed by or in consultation with a specialist in neurology, neuropsychiatry, or gerontology.
- The beneficiary has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment.
- The beneficiary has not had a stroke, transient ischemic attack (TIA), or seizures in the past 12 months.
- The physician attests to whether the beneficiary is actively abusing alcohol or cigarettes, and documentation is provided of the beneficiary's smoking history or alcohol or chronic substance use, including prescription medications, cannabis, or other illicit drugs.
- Behavioral health diagnoses have been assessed for contributions to memory deficits.

Alzheimer's disease (AD)

- The beneficiary has a recent diagnosis of mild cognitive impairment (MCI) due to AD or mild Alzheimer's dementia; **AND**
- The beneficiary has one of the following scores at baseline on any of following assessment tools:
  - 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; **OR**
  - Montreal Cognitive Assessment (MoCA) score 16-25
- The beneficiary has had a Positron Emission Tomography (PET) scan confirming the presence of amyloid beta plaque; **OR**

- The beneficiary lumbar puncture results confirming at least one of the following in cerebrospinal fluid (CSF) assessment:
  - Presence of elevated phosphorylated tau (P-tau) protein or elevated tau (T-tau) protein, and reduced beta amyloid-42 (Aβ 42); **OR**
  - Low Aβ 42/40 ratio; **OR**
  - Elevated P-tau/Aβ 42 ratio; **OR**
  - Elevated T-tau/Aβ 42 ratio; **AND**
- The beneficiary has had a recent brain magnetic resonance imaging (MRI) within one year prior to initiating treatment to evaluate for pre-existing amyloid related imaging abnormalities (ARIA).
- The beneficiary has had genotype testing prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier); **OR**
- Genotype testing has not been performed, and the physician has informed the beneficiary that it cannot be determined if they are a ApoE ε4 homozygote and, therefore, if they are at higher risk for developing ARIA.

EXCLUSIONS

- **Non-Alzheimer's dementia**: Cognitive impairment or dementia caused by other neurodegenerative diseases (e.g., Lewy body dementia, frontotemporal lobar degeneration, vascular dementia, metabolic impairment, traumatic brain injury, etc.).
- **Neurological and medical comorbidities**: Non-AD causes of cognitive impairment (chronic psychiatric illness, chronic cardiovascular disease, past history of psychotropic drug dependence)
- **MRI findings**: More than 4 microhemorrhages, any macrohemorrhage > 10 mm, superficial siderosis, vasogenic edema, multiple lacunar infarcts or major strokes, severe small vessel disease, or subcortical hyperintensities consistent with severe white matter disease (e.g., Fazekas score of 3).
- **Concurrent amyloid-targeting therapies**: Leqembi will not be used in combination with any other amyloid beta-directed antibodies (e.g., aducanumab, donanemab-azbt).
- **Anticoagulant therapies**: Beneficiaries who are currently receiving direct-acting oral anticoagulants (e.g., Apixaban, Dabigatran, Edoxaban, Rivaroxaban, etc.), anticoagulants (e.g., Factor Xa inhibitors), anti-platelet agents (with the exception of prophylactic aspirin or clopidogrel), or anti-thrombins (e.g., heparin, warfarin).
- **Bleeding disorder**: Bleeding disorder that is not under adequate control (including a platelet count less than 50,000 or INR greater than 1.5).
- **Advanced disease**: Beneficiaries whose dementia is too progressed (e.g., MMSE < 20).

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- MRI has been obtained prior to the 5th dose and shows no increase in size or number of ARIA.

- The beneficiary has responded to therapy compared to pretreatment baseline, as evidenced by improvement, stability, or slowing in cognitive or functional impairment in one or more of the following: MMSE, CDR-SB, MoCA, etc.
- The beneficiary has not progressed to moderate or severe AD.
- Additional MRIs will be required prior to the 7th and 14th doses to continue to screen for evidence of ARIA.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0174 – Injection, lecanemab-irmb, 1mg; 1 billable unit = 1 mg

LEQVIO (INCLISIRAN)

Updated: 09/27/2025

INDICATIONS

- **Heterozygous familial hypercholesterolemia (HeFH)**
- **Clinical atherosclerotic cardiovascular disease (ASCVD)**

CLINICAL CRITERIA

Note: AFMC to include review of pharmacy claims prior to decision

- The beneficiary is age 18 years of age or older
- The drug is prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
- The beneficiary has a documented diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) and requires additional lowering of low-density lipoprotein cholesterol (LDL-C); **OR**
  - The beneficiary has a diagnosis consistent with an FDA-approved indication
- The beneficiary should have LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe (Zetia), unless contraindicated
- A medically appropriate reason is provided why the beneficiary cannot use the following alternative pharmacy benefit agents indicated for their condition: PCSK9-inhibitors (e.g., Praluent, Repatha), ACL-inhibitors (e.g., Nexletol, Nexlizet)
- The medication will not be used in combination with PCSK9 inhibitors (e.g., Praluent, Repatha), microsomal triglyceride transfer protein inhibitors (e.g., Juxtapid), or angiopoietin-like 3 (ANGPTL3) inhibitors (e.g., Evkeeza)
- Documentation is provided that the beneficiary was screened for tobacco use at every visit.
  - If the beneficiary smokes tobacco, the provider will submit a smoking cessation plan or documentation that the beneficiary received tobacco cessation intervention, either through counseling or pharmacotherapy.

APPROVAL DURATION

Approval is for six months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has had a reduction in LDL-C compared to baseline labs (prior to initiating inclisiran)
- The beneficiary continues to adhere to diet and exercise therapy established prior to the original inclisiran approval
- Absence of unacceptable toxicity from therapy (e.g., severe injection site reactions)

BILLING/CODING INFORMATION

J1306 – Injection, inclisiran, 1 mg

LIBTAYO (CEMIPLIMAB-RWLC)

Updated: 10/09/2025

INDICATIONS

Libtayo is indicated for treatment of:

- **Cutaneous squamous cell carcinoma (CSCC)**
- **Basal cell carcinoma (BCC)**
- **Non-small cell lung cancer (NSCLC)**

NCCN CLINICAL PRACTICE GUIDELINES

- **Vulvar cancer**

CLINICAL CRITERIA

- The drug must be prescribed by an oncologist.
- The beneficiary is 18 years of age or older.
- The beneficiary has not experienced disease progression while on previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., atezolizumab, avelumab, durvalumab, nivolumab, etc.)

Cutaneous squamous cell carcinoma (CSCC)

- For the treatment of adult beneficiaries with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- For the adjuvant treatment of adult beneficiaries with CSCC at high risk of recurrence after surgery and radiation.

Basal cell carcinoma (BCC)

- For the treatment of adult beneficiaries with locally advanced or metastatic BCC (laBCC or mBCC) who have previously been treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

Non-small cell lung cancer (NSCLC)

- Used in combination with platinum-based chemotherapy for the first-line treatment of adult beneficiaries with non-small cell lung cancer (NSCLC) with no EGFR, ALK, or ROS1 aberrations that is:
  - Metastatic; **OR**
  - Locally advanced in beneficiaries who are not candidates for surgical resection or definitive chemoradiation
- Used as a single agent for the first-line treatment of adult beneficiaries with NSCLC whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%), as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, that are:
  - Metastatic; **OR**

- Locally advanced in beneficiaries who are not candidates for surgical resection or definitive chemoradiation.

NCCN RECOMMENDED INDICATIONS

Vulvar cancer

- Used as second-line or subsequent therapy for treatment of vulvar cancer

EXCLUSIONS

- Untreated brain metastasis that may be considered active.
- Allergic reactions or acute hypersensitivity reactions attributed to antibody treatments.
- Any medical co-morbidity, physical examination finding, metabolic dysfunction, or clinical laboratory abnormality that renders the beneficiary unsuitable for drug therapy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding positively to therapy (e.g., signs/symptom reduction, no disease progression)
- Absence of unacceptable toxicity from the drug (e.g., hepatic toxicity, grade 2 or higher pneumonitis, colitis, endocrinopathies, nephritis, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9119 − Injection, cemiplimab-rwlc, 1 mg; 1 billable units = 1 mg

LOQTORZI (TORIPALIMAB-TPZI)

Updated: 08/14/2024

INDICATIONS

Nasopharyngeal carcinoma (NPC)

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has one of the following:
  - Metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC)
    - Used in combination with cisplatin and gemcitabine
    - Used as a first-line treatment
  - Recurrent, unresectable or metastatic nasopharyngeal carcinoma (NPC)
    - Used as a single agent
    - Disease progression on or after a platinum-containing chemotherapy

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, severe immune-mediated adverse reactions, complications of allogenic hematopoietic stem cell transplantation [HSCT], solid organ transplant rejection, etc.)

DOSAGE / ADMINISTRATION

- For first-line treatment of metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC), in combination with cisplatin and gemcitabine:
  - 240 mg intravenously every three weeks until disease progression, unacceptable toxicity, or up to 24 months.
- For previously treated unresectable or metastatic NPC, as a single agent:
  - 3 mg/kg intravenously every two weeks until disease progression or unacceptable toxicity.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3263 – Injection, toripalimab-hyphentpzi, 1 mg
- J9060 – Injection, cisplatin, powder or solution, 10 mg
- J9196 – Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to J9201, 200 mg

- J9201 - Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg

LUCENTIS (RANIBIZUMAB)

Updated: 04/08/2025

INDICATIONS

Lucentis is indicated for treatment of:

- **Neovascular (wet) age-related macular degeneration (AMD)**
- **Macular edema following retinal vein occlusion (RVO)**
- **Diabetic macular edema (DME)**
- **Diabetic retinopathy**
- **Myopic choroidal neovascularization (mCNV)**

CLINICAL CRITERIA

- The beneficiary is free from ocular and peri-ocular infections.
- The beneficiary has a definitive diagnosis of one of the following:
  - Neovascular (wet) age-related macular degeneration (AMD)
  - Diabetic macular edema (DME)
  - Diabetic retinopathy
  - Macular edema following retinal vein occlusion (RVO)
  - Myopic choroidal neovascularization (mCNV)

OFF LABEL USES

- **Vitreous hemorrhage**
- **Retinopathy of prematurity (ROP)**
- Lucentis use in vitreous hemorrhage and retinopathy of prematurity are off label, per FDA prescribing indications. However, evidence from medical literature and prescribing guidelines indicate that intravitreal anti-VEGF agent use is safe and effective in its treatment.

APPROVAL DURATION

- Approval for myopic choroidal neovascularization (mCNV) will be provided for 3 months and may be renewed.
- Approval for all other indications will be provided for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary had a beneficial response to therapy.
- Continued administration is necessary for maintenance treatment of the condition.
- For myopic choroidal neovascularization ONLY:
  - Continued administration is necessary due to disease activity (e.g., decrease in vision, visual symptoms [e.g., metamorphopsia], or the presence of intra-/sub-retinal fluid or active leakage)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2778 – Injection, ranibizumab, 0.1 mg; 1 billable unit = 0.1 mg

LUMIZYME (ALGLUCOSIDASE ALFA)

Updated: 04/08/2025

INDICATIONS

Lymizume (alglucosidase alfa) is indicated for:

- **Pompe disease (GAA deficiency)**

CLINICAL CRITERIA

- Diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency) confirmed by one of the following:
  - Enzyme assay confirming low GAA activity
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing
- Documented baseline 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), or 6-minute walk test (6MWT); **OR**
  - Late-onset (non-infantile) disease: FVC or 6MWT

APPROVAL DURATION

Coverage is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g. severe allergic and anaphylactic reactions, severe cutaneous and systemic immune-medicated reactions, acute cardiorespiratory failure, cardiac arrhythmia, etc.).
- No evidence that the beneficiary has developed IgG antibodies to alglucosidase alfa at a sustained titer level of ≥ 12,800.
- The beneficiary has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - Infantile-onset disease:
    - Stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, or 6MWT
  - Late-onset (non-infantile) disease:
    - Stabilization or improvement in FVC or 6MWT

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0221 – Injection, alglucosidase alfa (lumizyme), 10 mg; 1 billable unit = 10 mg

ICD-10 Code

- E74.02 – Pompe disease

LUTATHERA (LUTETIUM LU 177 DOTATATE)

Updated: 04/08/2025

INDICATIONS

Lutathera is indicated for treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults and pediatric beneficiaries 12 years of age or older.

CLINICAL CRITERIA

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

- The beneficiary is at least 12 years of age
- The beneficiary has experienced disease progression despite receiving somatostatin analog therapy (octreotide or lanreotide)
- The beneficiary has locally advanced, inoperable, or metastatic well-differentiated neuroendocrine tumor.
- The beneficiary's disease is somatostatin receptor-positive in all tumor lesions, as detected by Octreotide scintigraphy (OctreoScan), dotatate PET scan, somatostatin receptor-positive (SSTR)-PET/CT, or SSTR-PET/MR scan.
- The drug is prescribed by or in consultation with an oncologist.

OFF-LABEL INDICATIONS (SUPPORTED BY NCCN GUIDELINES)

Pheochromocytoma or paraganglioma

- The beneficiary is 18 years of age or older.
- The beneficiary has somatostatin receptor-positive, locally advanced, unresectable, or metastatic disease.
- The drug is prescribed by or in consultation with an oncologist.

Bronchopulmonary or thymus neuroendocrine tumors (NETS)

- The beneficiary is 18 years of age or older.
- The disease is locally advanced, unresectable, or metastatic.
- The beneficiary has experienced disease progression, despite receiving somatostatin analog therapy (octreotide or lanreotide)
- The drug is prescribed by or in consultation with an oncologist.

DOSING

- Administer 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses.
- Administer long-acting octreotide 30 mg intramuscularly (IM) 4 to 24 hours after each Lutathera dose and short-acting octreotide for symptomatic management.
- Continue long-acting octreotide 30 mg IM every 4 weeks after completing Lutathera until disease progression or for up to 18 months following treatment initiation.

APPROVAL DURATION

Approval is for 8 months (4 doses only) and may **NOT** be renewed.

RENEWAL/REAUTHORIZATION

May **NOT** be renewed.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- A9699 – Radiopharmaceutical, therapeutic, not otherwise classified
- C9031 – Lutetium Lu 177, dotatate, therapeutic, 1 mCi (Hospital Outbeneficiary Use ONLY)

LUXTURNA (VORETIGENE NEPARVOVEC-RZYL)

Updated: 04/08/2025

INDICATIONS

Luxturna is indicated for the treatment of beneficiaries with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Beneficiaries must have viable retinal cells, as determined by the treating physician.

CLINICAL CRITERIA

- The beneficiary is 4 years of age or older.
- Prior to administration, the beneficiary must have documentation of sufficient and viable retinal cells.
- The beneficiary must have a definitive diagnosis of biallelic RPE65 mutation-associated retinal dystrophy that is confirmed by genetic testing for biallelic mutation of the REP65 gene. Testing may specifically reference any of the following:
  - Amaurosis congenita of Leber II
  - Amaurosis congenita of Leber, type 2
  - Leber congenital amaurosis 2 (LCA2)
  - Retinitis pigmentosa 20
- Diminished functional vision in each eye, as evaluated by clinical outcome of **any one** of the following:
  - Best corrected visual acuity of 20/60 or worse
  - Visual field less than 20 degrees in any meridian, as measured by a III4e isopter or equivalent
- The beneficiary has viable retinal cells, as determined by non-invasive means, such as optical coherence tomography (OCT) or ophthalmoscopy indicating **any one** 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 a III4e isopter or equivalent

EXCLUSIONS

- Pregnancy in female beneficiaries
- The beneficiary is breastfeeding
- Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the RPE65 enzyme (individuals who discontinue use of these compounds for 18 months may become eligible)
- Prior intraocular surgery within 6 months
- Pre-existing eye conditions or complicating systemic disease that would preclude the planned surgery or interfere with the interpretation of study.
  - Complicating systemic diseases include those in which the disease itself, or the treatment for the disease, can alter ocular function. Examples include the following:
    - Malignancies for which treatment could affect central nervous system function (e.g. radiotherapy of the orbit, leukemia with central nervous system/optic nerve involvement)

- Beneficiaries with diabetes or sickle cell disease are excluded if they have any manifestation of advanced retinopathy (e.g. macular edema, proliferative changes)
- Beneficiaries with immunodeficiency (acquired or congenital) can be susceptible to opportunistic infection (e.g. cytomegalovirus retinitis)

APPROVAL DURATION

Coverage will be provided for each eye 1.5 x 10^{12} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL, and may not be renewed

RENEWAL/REAUTHORIZATION

Luxturna is considered **NOT** medically appropriate for renewal

BILLING/CODING INFORMATION

Applicable Procedure Codes

- C9399 – Unclassified drugs or biologicals
- J3490 – Unclassified drugs
- J3590 – Unclassified biologics

ICD-10 Diagnosis Code

- H35.50 – Unspecified hereditary retinal dystrophy
- H35.52 – Pigmentary retinal dystrophy
- H35.54 – Dystrophies primarily involving the retinal pigment epithelium

MARQIBO (VINCRISTINE SULFATE LIPOSOMAL)

Updated: 04/19/2024

INDICATIONS

Marqibo is indicated for treatment of adult beneficiaries with

- **Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL)**

CLINICAL CRITERIA

Acute lymphoblastic leukemia (ALL)

- The beneficiary is 18 years of age or older
- The beneficiary does not have any pre-existing demyelinating conditions (e.g., Charcot-Marie-Tooth syndrome)
- The drug is used as single agent therapy
- The drug is used for second or greater relapse, or refractory disease after 2 or more anti-leukemia therapies (e.g., regimens containing doxorubicin, daunorubicin, cyclophosphamide, cytarabine, vincristine, asparaginase, clofarabine, etc.)
- The beneficiary's disease is Philadelphia chromosome-negative (Ph-)

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

APPROVAL DURATION

Authorization is for six months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Stabilization of disease or absence of progression of disease
- Absence of unacceptable toxicity from the drug (e.g., peripheral motor and sensory neuropathy, central and autonomic neuropathy, myelosuppression [e.g., neutropenia, thrombocytopenia, or anemia], tumor lysis syndrome, elevated liver function tests [ALT, AST, and bilirubin], etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9371 – Injection, vincristine sulfate liposome, 1 mg; 1 mg = 1 billable unit

MONJUVI (TAFASITAMAB-CXIX)

Updated: 06/19/2025

INDICATIONS

Monjuvi is indicated for treatment of:

- **Diffuse large B-cell lymphoma (DLBCL)**
- **Follicular lymphoma (FL)**

CLINICAL CRITERIA

Diffuse large B-cell lymphoma (DLBCL)

- Used in combination with lenalidomide for the treatment of adult beneficiaries with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, in beneficiaries who are not eligible for autologous stem cell transplant (ASCT).

Follicular lymphoma (FL)

- Used in combination with lenalidomide and rituximab for adults with relapsed or refractory follicular lymphoma.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Beneficiary response to treatment or disease progression
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, infections, second primary malignancies, etc.).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9349 – Injection, tafasitamab-cxix, 2 mg

MOZOBIL (PLERIXAFOR)

Updated: 04/19/2024

INDICATIONS

Mozobil is indicated in combination with filgrastim (granulocyte-colony stimulating factor [G-CSF]) to mobilize hematopoietic stem cell (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in beneficiaries with:

- **Non-Hodgkin lymphoma**
- **Multiple myeloma**

CLINICAL CRITERIA

- The beneficiary is diagnosed with non-Hodgkin lymphoma or multiple myeloma.
- The drug must be used in combination with a granulocyte-colony stimulating factor (e.g., Neupogen [filgrastim], Zarxio [filgrastim-sndz], Nivestym [filgrastim-aafi], Granix [tbo-filgrastim], etc.)

APPROVAL DURATION

Authorization is for one treatment cycle of four days and is eligible for renewal for one additional treatment cycle.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions/anaphylaxis, leukocytosis, thrombocytopenia, splenic enlargement/rupture, tumor cell mobilization, etc.)
- The beneficiary has had only 1 previous treatment cycle.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2562 – Injection, plerixafor, 1 mg: 1 billable unit = 1 mg

MYLOTARG (GEMTUZUMAB OZOGAMICIN)

Updated: 04/19/2024

INDICATIONS

Mylotarg is indicated for:

- Treatment of newly diagnosed CD33-positive **acute myeloid leukemia (AML)** in adult and pediatric beneficiaries 1 month of age or older.
- Treatment of **relapsed or refractory CD33-positive AML** in adults and in pediatric beneficiaries 2 years of age or older.

CLINICAL CRITERIA

- Beneficiary has CD33-positive disease.
- The beneficiary has a history of or predisposition for QTc prolongation and has a baseline electrocardiogram (ECG)
- The beneficiary has hyperleukocytosis (leukocyte count ≥ 30 x 10^9/L) and has had cytoreduction.
- The drug is prescribed by or in consultation with a hematologist or oncologist.

APPROVAL DURATION

- For newly diagnosed AML:
  - De novo disease in combination with daunorubicin and cytarabine:
    - Approval is provided for 6 months consisting of 3 cycles (1 induction and 2 consolidation) and may **not** be renewed.
  - Single-agent use:
    - Approval is provided for 6 months and may be renewed. Approval is for 1 cycle of induction and up to a maximum of 8 cycles of continuation.
- For relapsed or refractory AML:
  - Approval is provided for 6 months consisting of one cycle (3 doses) and may **not** be renewed.

RENEWAL/REAUTHORIZATION

Treatment of newly diagnosed de novo AML as well as relapsed or refractory AML **are not renewable**.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9203 – Injection, gemtuzumab ozogamicin, 0.1 mg: 1 billable unit = 0.1 mg

MYOZYME (ALGLUCOSIDASE ALFA)

Updated: 04/19/2024

INDICATIONS

Myozume (alglucosidase alfa) is indicated for:

- **Pompe disease (GAA deficiency)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency) confirmed by one of the following:
  - Enzyme assay confirming low GAA activity.
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing
- The beneficiary has documented baseline values for one or more of the following:
  - Infantile-onset disease: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced ital capacity (FVC), and or 6-minute walk test (6MWT); **OR**
  - Late-onset (non-infantile) disease: FVC or 6MWT

APPROVAL DURATION

Coverage is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g. severe allergic and anaphylactic reactions, severe cutaneous and systemic immune-medicated reactions, acute cardiorespiratory failure, cardiac arrhythmia, etc.)
- The beneficiary has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - Infantile-onset disease:
    - Stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, or 6MWT
  - Late-onset (non-infantile) disease:
    - Stabilization or improvement in FVC or 6MWT

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0220 – Injection, alglucosidase alfa (myozyme), 10 mg; 1 billable unit = 10 mg

ICD-10 Code

- E74.02 – Pompe disease

NAGLAZYME (GALSULFASE)

Updated: 04/19/2024

INDICATIONS

Naglazyme is indicated for treatment of:

- **Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome)**

CLINICAL CRITERIA

Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome)

- The beneficiary is 5 years of age or older.
- The beneficiary has a definitive diagnosis of MPS VI confirmed by one of the following:
  - Arylsulfatase B (ARSB) enzyme activity of < 10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes; **OR**
  - Detection of pathogenic mutations the ARSB gene by molecular genetic testing
- The beneficiary has a documented baseline 12-minute walk test (12-MWT) or a 3-minute stair climb test.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by improvement in 12-MWT or 3-minute stair climb test compared to pre-treatment baseline
- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and allergic reactions, immune-mediated reactions, acute respiratory complications, acute cardiorespiratory reactions, severe infusion reactions, spinal or cervical cord compression).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1458 – Injection, galsulfase, 1 mg; 1 billable unit = 1 mg

NEXVIAZYME (AVALGLUCOSIDASE ALFA-NGPT)

Updated: 10/13/2025

INDICATIONS

Nexviazyme is indicated for the treatment of beneficiaries 1 year of age or older with late-onset **Pompe disease** (lysosomal acid alpha-glucosidase [GAA] deficiency)

CLINICAL CRITERIA

- The beneficiary has a diagnosis of non-infantile onset (late-onset) Pompe disease, confirmed either by an enzyme assay confirming low acid alpha-glucosidase (GAA) deficiency or by 2 confirmed GAA gene mutations.
- The beneficiary is 1 year of age or older.
- The beneficiary displays clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.).
- The beneficiary has documentation of forced vital capacity (FVC) 30-85% of predicted value.
- The beneficiary is able to walk 40 meters on a 6-minute walk test (6MWT) without assistive devices.
- Nexviazyme will not be used in combination with other enzyme replacement therapies (e.g., alglucosidase-alfa).
- The drug is prescribed by or in consultation with a geneticist, neurologist, metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of positive clinical response, such as improved or stabilized respiratory muscle strength (i.e., forced vital capacity [FVC]) or functional endurance (e.g., 6-minute walk test).

RECOMMENDED DOSING

- ONE of the following dosing regimens can be approved based on the beneficiary's actual body weight:
  - For beneficiaries ≥ 30 kg: Dose is 20 mg/kg administered by intravenous infusion once every 2 weeks; **OR**
  - For beneficiaries < 30 kg: Dose is 40 mg/kg administered by intravenous infusion once every 2 weeks.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0219 – Injection, avalglucosidase alfa-ngpt, 4 mg

NIKTIMVO (AXATILIMAB-CSFR)

Updated: 02/25/2025

INDICATIONS

Chronic graft-versus-host disease (cGVHD)

- Niktimvo is indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric beneficiaries weighing at least 40 kg.

CLINICAL CRITERIA

- Niktimvo is prescribed by or in consultation with a hematologist, oncologist, or transplant specialist.
- The beneficiary weighs at least ≥ 40 kg.
- The beneficiary has a diagnosis of chronic graft-versus-host disease (cGVHD).
- The beneficiary has tried and failed at least two conventional systemic treatments for chronic graft-versus-host disease. Examples of systemic therapy include the following:
  - Ruxolitinib (Jakafi)
  - Abatacept
  - Belumosudil (Rezurock)
  - Calcineurin inhibitors (e.g., tacrolimus, cyclosporine)
  - Hydroxychloroquine (Plaquenil)
  - Ibrutinib (Imbruvica)
  - Imatinib (Gleevec)
  - Interleukin-2 (e.g., Proleukin, Aldesleukin),
  - Methotrexate
  - mTOR inhibitors (e.g., sirolimus, everolimus)
  - Mycophenolate mofetil
  - Pentostatin (Nipent)
  - Rituximab
- Documentation of specific therapies tried, duration of treatment, and reason for discontinuation (e.g., lack of efficacy, adverse effects) is provided.

EXCLUSIONS

Niktimvo for any other indication or use is considered not medically necessary. Excluded indications include the following:

- Treatment of acute graft-versus-host-disease
- Treatment of cGVHD in beneficiaries weighing less than 40 kg
- Treatment of cGVHD as first- or second-line therapy
- Treatment of any condition other than cGVHD

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that the beneficiary has experienced clinical benefit from therapy, as evidenced by at least one of the following:
  - Improvement in cGVHD symptoms
  - Reduction in immunosuppressive medication requirements
- Absence of unacceptable toxicity from Niktimvo (e.g., severe infusion related reactions, etc.).

RECOMMENDED DOSING

Approval is for 0.3 mg/kg (up to a maximum dose of 35 mg) given as an intravenous infusion once every 2 weeks until progression or unacceptable toxicity.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9038 – Injection, axatilimab-csfr, 0.1 mg (effective date April 1, 2025)

NPLATE (ROMIPLOSTIM)

Updated: 04/05/2024

INDICATIONS

Nplate is indicated for treatment of **thrombocytopenia** in:

- Adult beneficiaries with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Pediatric beneficiaries 1 year of age or older with ITP for at least 6 months who have had insufficient response to corticosteroids, immunoglobulins, or splenectomy

Note: Nplate is indicated to increase survival in adults and in pediatric beneficiaries (including term neonates) acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation [HS-ARS]).

CLINICAL CRITERIA

Immune thrombocytopenia (ITP)

- The beneficiary has platelet count less than 30,000 mm^3; **OR**
  - Platelet count less than 50,000 mm^3 AND clinical condition that increases the risk for bleeding; **AND**
- The beneficiary has had inadequate response to or is not a candidate for an initial treatment option (e.g., corticosteroids, immunoglobulins, rituximab, splenectomy)

NCCN RECOMMENDED USES

Myelodysplastic syndromes (MDS)

- The drug is prescribed by or in consultation with an oncologist or hematologist.
- The beneficiary has lower-risk MDS (IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]).
- The beneficiary has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (e.g., azacitadine decitabine) or immunosuppressive therapy (e.g., Atgam, cyclosporine).

OTHER OFF-LABEL USES

Adult beneficiary with chemotherapy-induced thrombocytopenia (CIT)

- The beneficiary has platelet count less than 100,000 mm^3 **AND**
  - The drug is being used following a delay in chemotherapy related to thrombocytopenia; **OR**
  - Following the last chemotherapy administration, the beneficiary has experienced thrombocytopenia for more than 3 weeks.

Note: Nplate (romiplostim) is currently limited to **ADULT** beneficiaries 18 years of age and older.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of beneficial clinical response, as evidenced by increased platelet counts.
- The beneficiary continues to remain at risk for bleeding complications.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2796 – Injection, romiplostim, 10 mcg; 10 mcg = 1 billable unit

NUCALA (MEPOLIZUMAB)

Updated: 09/25/2025

INDICATIONS

Nucala is indicated for:

- **Severe eosinophilic asthma**
- **Chronic rhinosinusitis with nasal polyps**
- **Chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype**
- **Eosinophilic granulomatosis with polyangiitis (EGPA) (Churg-Strauss syndrome)**
- **Hypereosinophilic syndrome (HES)**

CLINICAL CRITERIA

- For add-on maintenance treatment of adult and pediatric beneficiaries 6 years of age or older with severe asthma and with an eosinophilic phenotype
- For add-on maintenance treatment of adult beneficiaries 18 years of age or older with chronic rhinosinusitis with nasal polyps
- For add-on maintenance treatment of adult beneficiaries 18 years of age or older with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
- For treatment of adult beneficiaries 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA)
- For treatment of adult and pediatric beneficiaries 12 years of age or older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause

EXCLUSIONS

Nucala may not be approved when prescribing indications are not met **OR** for the following conditions:

- Acute bronchospasm
- Aspirin-exacerbated respiratory disease (AERD)
- Allergic bronchopulmonary aspergillosis
- Atopic dermatitis
- Eosinophilic esophagitis
- Severe allergic asthma (without documentation of severe eosinophilia)
- Status asthmaticus

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Treatment with Nucala (mepolizumab) has resulted in clinical improvement as documented by one or more of the following:
  - Decreased utilization of rescue medications

- Decreased frequency of exacerbations defined as worsening of asthma that requires an increase in:
  - ICS dose or treatment with systemic corticosteroids
  - Hospitalizations
  - Emergency department visits
  - Unscheduled visits to health care provider
- Increase in predicted FEV1 from pretreatment baseline
- Reduction in reported asthma-related symptoms (e.g., asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing)

BILLING/CODING INFORMATION

Applicable service codes:

- J2182 – Injection, mepolizumab, 1 mg: 1 billable unit = 1 mg

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

Updated: 11/07/2025

INDICATIONS

Ocrevus is indicated for treatment of:

- **Relapsing-remitting multiple sclerosis (RRMS)**
  - Relapsing-remitting MS (RRMS) includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
- **Primary progressive multiple sclerosis (PPMS)**
  - Primary progressive MS (PPMS) is characterized by continuous worsening neurologic function from symptom onset.

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The drug is used as single agent therapy.
- The beneficiary has a confirmed diagnosis of primary progressive multiple sclerosis, as documented by laboratory report or test (e.g., MRI, CSF, etc.); **OR**
- The beneficiary has a confirmed diagnosis of relapsing form of multiple sclerosis (e.g., relapsing-remitting MS [RRMS] or secondary progressive MS [SPMS] with relapses)
- The beneficiary has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment AND the beneficiary does not have active disease (e.g., positive for HBsAg and anti-HBV tests)
- The beneficiary will not receive live vaccines concurrently with ocrelizumab.

EXCLUSIONS

- The beneficiary has active hepatitis B disease
- The beneficiary has active infection
- The beneficiary receiving live vaccines

APPROVAL DURATION

Authorization is for 6 months and is eligible for renewal.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is not receiving 2 or more disease modifying drugs for multiple sclerosis.
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, severe infections, malignancy, etc.)
- Documentation of positive clinical response to therapy, as demonstrated by clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

BILLING/CODING INFORMATION

Applicable service codes:

- J3490 – Unclassified drugs
- J3590 – Unclassified biologics
- C9494 – Injection, ocrelizumab, 1 mg
- J2350 – Injection, ocrelizumab, 1 mg

Note: CMS has not yet assigned a product-specific HCPCS code or J-code for Ocrevus Zunovo

OMVOH (MIRIKIZUMAB-MRKZ)

Updated: 03/28/2025

INDICATIONS

Omvoh is indicated for the treatment of:

- Moderately to severely active **ulcerative colitis** in adults.
- Moderately to severely active **Crohn's disease** in adults.

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The drug is prescribed by or in consultation with a gastroenterologist.
- For induction of remission:
  - The beneficiary has had a trial (at least 4 weeks) of an oral systemic corticosteroid equivalent to 40-60 mg/day prednisone with a planned dose taper; **OR**
  - The beneficiary has had an inadequate response within 3-5 days of an intravenous corticosteroid (IVCS) equivalent to 60 mg/day methylprednisolone or 100 mg hydrocortisone 3-4 times per day for the induction of remission.
- For maintenance of remission:
  - The beneficiary has had a trial of one systemic agent for Ulcerative Colitis or Crohn's Disease (e.g., 6-mercaptopurine, azathioprine, etc.) and failed to achieve mucosal healing within 4 months or had a relapse.
- The beneficiary will not be using Omvoh in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors [see **table** below for agent list]); **OR**
- The beneficiary will be using Omvoh in combination with another immunomodulatory agent; **AND**
  - The prescribing information for Omvoh does not limit the use with another immunomodulatory agent; **AND**
  - The prescribing physician has provided information in support of combination therapy (e.g., clinical trials, phase III studies, guidelines, etc.).

Immunomodulating Biologic Agents/Janus Kinase (JAK) Inhibitors
Actemra (tocilizumab)
Adbry (tralokinumab)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibingo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)

Immunomodulating Biologic Agents/Janus Kinase (JAK) Inhibitors
Humira (adalimumab) and biosimilars
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizuab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Remicade (inflimimab) and biosimiliars (Avsola, Inflectra, Ixifi, Renflexis)
Rinvoq (upadacitinib)
Rituxan (rituximab) and biosimilars (Riabni, Ruxience, Truxima)
Rituxan Hycela (rituximab/hyaluronidase)
Saphnelo (anifrolumab
Siliq (brodalumab)
Simponi (golimumab)
Simponi Aria (golimumab)
Skyrizi (risankizumab-rzaa
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib)
Xolair (omalizumab)

RECOMMENDED DOSAGE

Ulcerative colitis

- Initial IV induction: 300 mg IV at 0, 4, and 8 weeks.
- SC maintenance: 200 mg SC at week 12, and every 4 weeks thereafter.

Crohn's disease

- Initial IV induction: 900 mg IV at 0, 4, and 8 weeks.
- SC maintenance: 300 mg SC at week 12, and every 4 weeks thereafter.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation from requesting provider of positive beneficiary response to therapy (e.g., endoscopic evidence of mucosal healing)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590, C9399 - Omvoh (mirikizumab-mrkz injection for subcutaneous use).

ONCASPAR (PEGASPARGASE)

Updated: 09/25/2025

INDICATIONS

Oncaspar is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult beneficiaries with **acute lymphoblastic leukemia** and hypersensitivity to native forms of L-asparaginase.

CLINICAL CRITERIA

- **Acute lymphoblastic leukemia**
  - The beneficiary has a diagnosis of acute lymphoblastic leukemia (ALL).
  - Oncaspar is being prescribed by or in consultation with an oncologist or hematologist.
  - The beneficiary is 1 month of age or older.
  - The beneficiary does not have a history of serious hypersensitivity reactions to Oncaspar.
  - The beneficiary does not have a history of serious thrombosis with prior L-asparaginase therapy.
  - The beneficiary does not have a history of pancreatitis with prior L-asparaginase therapy.
  - The beneficiary does not have a history of serious hemorrhagic events with prior L-asparaginase therapy.
  - The beneficiary does not have severe hepatic impairment.
  - Oncaspar is used as a component of a multi-agent chemotherapy regimen.

COMPENDIAL PRESCRIBING CONSIDERATIONS

- **T-cell lymphoma**
  - Extranodal natural killer/T-cell lymphoma (ENKL)
  - Aggressive NK-cell leukemia (ANKL)
  - Hepatosplenic T-cell lymphoma
- The drug is prescribed by or in consultation with an oncologist or hematologist.
- The drug is prescribed as a component of any of the following:
  - Modified-SMILE (steroid [dexamethasone], methotrexate, ifosfamide, pegaspargase, etoposide)
  - P-GEMOX (gemcitabine, pegaspargase, oxaliplatin)
  - DDGP (dexamethasone, cisplatin, gemcitabine, pegaspargase)
  - AspaMetDex (pegaspargase, methotrexate, dexamethasone)

EXCLUSIONS

Use of Oncaspar in combination with an anti-PD-1 antibody and anlotinib with radiotherapy for the treatment of natural killer/T-cell lymphoma.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, defined by stabilization of disease and the beneficiary not showing evidence of progressive disease while on therapy.
- Absence of unacceptable toxicity from Oncaspar (e.g., anaphylaxis and serious hypersensitivity reactions, serious thrombotic events, pancreatitis, glucose intolerance, hemorrhage, hepatotoxicity, etc.)

RECOMMENDED DOSING

- Oncaspar (pegaspargase) is administered intramuscularly or intravenously no more frequently than every 14 days. Recommended dosages are:
  - For beneficiaries ≤ 21 years of age: 2,500 IU/m^2
  - For beneficiaries > 21 years of age: 2,000 IU/m^2

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9266 - Injection, pegaspargase, per single-dose vial; 1 billable unit = 1 vial

ONIVYDE (IRINOTECAN)

Updated: 03/28/2025

INDICATIONS

Onivyde is indicated for treatment of:

- **Pancreatic adenocarcinoma**

CLINICAL CRITERIA

- Used in combination with oxaliplatin, fluorouracil, and leucovorin for the first-line treatment of adult beneficiaries with metastatic pancreatic adenocarcinoma.
- Used in combination with fluorouracil and leucovorin for the treatment of adult beneficiaries with metastatic pancreatic adenocarcinoma after disease progression following gemcitabine-based therapy.

LIMITATIONS OF USE

Onivyde is not indicated as a single agent for the treatment of beneficiaries with metastatic pancreatic adenocarcinoma.

EXCLUSIONS

Beneficiaries with interstitial lung disease

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe diarrhea [grade 2-4], severe neutropenia [absolute neutrophil count below 1500/mm^3], pulmonary toxicity [interstitial lung disease], severe hypersensitivity reactions, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9205 – Injection, irinotecan liposome, 1 mg: 1 billable unit = 1 mg

OPDIVO (NIVOLUMAB)

Updated: 11/20/2025

INDICATIONS

Opdivo is indicated for:

- **Melanoma**
- **Non-small cell lung cancer (NSCLC)**
- **Small cell lung cancer (SCLC)**
  - **Note**: Opdivo was withdrawn in 2020 as an FDA-approved indication for the treatment of beneficiaries with small cell lung cancer (SCLC). However, NCCN guidelines list Opdivo as an option as subsequent therapy under “Other Recommended Regimens.”
- **Malignant pleural mesothelioma**
- **Renal cell carcinoma (RCC)**
- **Classical Hodgkin lymphoma (cHL)**
  - Indicated for adult and pediatric beneficiaries 12 years of age or older with classical Hodgkin lymphoma that has relapsed or progressed after:
    - Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; **OR**
    - 3 or more lines of systemic therapy that include autologous HSCT
- **Squamous cell carcinoma of the head and neck (SCCHN)**
- **Urothelial carcinoma**
- **Colorectal cancer** (also includes anal adenocarcinoma, appendiceal adenocarcinoma, small bowel adenocarcinoma)
- **Hepatocellular carcinoma (HCC)**
- **Esophageal squamous cell carcinoma (ESCC)**
- **Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**

CLINICAL CRITERIA

Authorization is provided in the following conditions:

- The drug must be prescribed by an oncologist.
- The beneficiary must be 18 years of age or older (unless otherwise specified)
- The beneficiary has not experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (other than when used as second-line or subsequent therapy for metastatic or unresectable melanoma in combination with ipilimumab following progression on single-agent anti-PD-1 immunotherapy).
- **Melanoma**
  - Used as a single agent or in combination with ipilimumab (Yervoy) for adult and pediatric beneficiaries 12 years of age or older with unresectable or metastatic melanoma,
  - For the adjuvant treatment of adult and pediatric beneficiaries 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.
- **Non-small cell lung cancer (NSCLC)**

- Used in combination with platinum-double chemotherapy for adult beneficiaries with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting
- For adult beneficiaries with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by single-agent OPDIVO as adjuvant treatment after surgery
- Used as first-line treatment in combination with ipilimumab (Yervoy) for adult beneficiaries with metastatic or recurrent non-small cell lung cancer expressing PD-L1 (≥ 1%), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations
- Used as first-line treatment, in combination with ipilimumab (Yervoy) and 2 cycles of platinum-doublet chemotherapy, in adult beneficiaries with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- For treatment of beneficiaries with metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Beneficiaries with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo.

- **Malignant pleural mesothelioma**
  - Used as first-line treatment in combination with ipilimumab (Yervoy) in adult beneficiaries with unresectable malignant pleural mesothelioma
- **Renal cell carcinoma (RCC)**
  - Used as a first-line treatment in combination with ipilimumab (Yervoy) in adult beneficiaries with intermediate or poor risk advanced renal cell carcinoma
  - Used as a first-line treatment in combination with cabozantinib in adult beneficiaries with advanced renal cell carcinoma
  - For treatment of advanced renal cell carcinoma in adult beneficiaries who have received prior anti-angiogenic therapy.
- **Classical Hodgkin lymphoma (cHL)**
  - For treatment of adult beneficiaries with classical Hodgkin lymphoma that has relapsed or progressed after:
    - Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; **OR**
    - 3 or more lines of systemic therapy that include autologous HSCT
- **Squamous cell carcinoma of the head and neck (SCCHN)**
  - For treatment of adult beneficiaries with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy.
- **Urothelial carcinoma**
  - For adjuvant treatment of urothelial carcinoma (UC) in adult beneficiaries who are at high risk of recurrence after undergoing radical resection of UC
  - Used as first-line treatment in combination with cisplatin and gemcitabine in adult beneficiaries with unresectable or metastatic urothelial carcinoma
  - For treatment of locally advanced or metastatic urothelial carcinoma in adult beneficiaries who:
    - Have disease progression during or following platinum-containing chemotherapy

    - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
- **Colorectal cancer, including appendiceal carcinoma and anal adenocarcinoma**
  - Used in combination with ipilimumab (Yervoy) for treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient dMMR metastatic colorectal cancer (CRC) in adult and pediatric beneficiaries 12 years of age or older
  - Used to treat microsatellite instability-high (MSI-H) or mismatch repair deficient dMMR metastatic colorectal cancer (CRC) that has progressed following treatment with oxaliplatin, irinotecan, and a fluoropyrimidine in adult and pediatric beneficiaries 12 years of age or older
- **Hepatocellular carcinoma (HCC)**
  - Used in combination with ipilimumab (Yervoy) for first-line treatment of unresectable or metastatic HCC in adult beneficiaries
- **Esophageal squamous cell carcinoma (ESCC)**
  - Used as treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in beneficiaries with who have received neoadjuvant chemoradiation.
  - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment of beneficiaries with unresectable advanced or metastatic esophageal squamous cell carcinoma
  - Used as first-line treatment in combination with ipilimumab (Yervoy) in beneficiaries with unresectable advanced or metastatic esophageal squamous cell carcinoma
  - Used as treatment of beneficiaries with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy
- **Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**
  - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy in beneficiaries with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma

NCCN RECOMMENDATIONS

- **Pediatric diffuse high-grade gliomas**
  - Used as adjuvant treatment of hypermutant tumor pediatric diffuse high-grade glioma or for recurrent or progressive disease
- **Rectal cancer**
  - Used as a single agent for neoadjuvant/definitive treatment of dMMR/MSI-H rectal cancer if the beneficiary has not received previous treatment with a checkpoint inhibitor. For up to 6 months only
- **Small cell lung cancer (SCLC)**
  - For treatment of beneficiaries with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy
- **Tumor mutational burden-high (TMB-H) cancer**
  - For the treatment of adult and pediatric beneficiaries with unresectable or metastatic tumor mutational burden-high (TMB-H) (> 10 mutations/megabase [mut/MB]) solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options

- **Classic Hodgkin lymphoma: Stage III–IV (advanced stage)**
  - Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD) as first-line therapy for Stage III/IV disease

APPROVAL DURATION

Approval is for 6 months and may be renewed, unless otherwise noted (e.g., NCCN recommendation for rectal cancer is limited to 6 months only, no renewal).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding positively to therapy (e.g., labs, signs/symptom reduction)
- No unacceptable toxicity to the drug

BILLING/CODING INFORMATION

Applicable service codes:

- J9299 – Injection, nivolumab, 1 mg; 1 billable unit = 1 mg

OPDIVO QVANTIG (NIVOLUMAB AND HYALURONIDASE-NVHY)

Updated: 11/03/2025

INDICATIONS

Opdivo Qvantig is indicated for:

- **Renal cell carcinoma (RCC)**
- **Melanoma**
- **Non-small cell lung cancer (NSCLC)**
- **Small cell lung cancer (SCLC)**
- **Squamous cell carcinoma of the head and neck (SCCHN)**
- **Urothelial carcinoma**
- **Colorectal cancer**
- **Hepatocellular carcinoma (HCC)**
- **Esophageal cancer**
- **Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**

CLINICAL CRITERIA

Authorization is provided in the following conditions:

- The drug must be prescribed by an oncologist.
- The beneficiary must be 18 years of age or older (unless otherwise specified)
- The beneficiary has not experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (other than when used as second-line or subsequent therapy for metastatic or unresectable melanoma in combination with ipilimumab following progression on single-agent anti-PD-1 immunotherapy).
- **Renal cell carcinoma (RCC)**
  - For adult beneficiaries with intermediate or poor risk advanced RCC, used as first-line treatment following combination treatment with intravenous nivolumab and ipilimumab (Yervoy)
    - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.
  - For adult beneficiaries with advanced renal cell carcinoma, used as a first-line treatment in combination with cabozantinib
  - For adult beneficiaries with advanced renal cell carcinoma who have received prior anti-angiogenic therapy
- **Melanoma**
  - For adult beneficiaries with unresectable or metastatic melanoma
  - For adult beneficiaries with unresectable or metastatic melanoma following combination treatment with intravenous nivolumab and ipilimumab (Yervoy)
    - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.
  - For the adjuvant treatment of adult beneficiaries with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma

- **Non-small cell lung cancer (NSCLC)**
  - For adult beneficiaries with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, used in combination with platinum-double chemotherapy
  - For adult beneficiaries with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements, used for neoadjuvant treatment in combination with platinum-doublet chemotherapy and followed by Opdivo Qvantig monotherapy as adjuvant treatment after surgery
  - For adult beneficiaries with metastatic NSCLC and progression on or after platinum-based chemotherapy. Beneficiaries with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo Qvantig.
    - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.
- **Squamous cell carcinoma of the head and neck (SCCHN)**
  - For adult beneficiaries with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy
- **Urothelial carcinoma**
  - Used for adjuvant treatment of urothelial carcinoma (UC) in adult beneficiaries who are at high risk of recurrence after undergoing radical resection of UC.
  - For adult beneficiaries with unresectable or metastatic urothelial carcinoma, used as first-line treatment in combination with cisplatin and gemcitabine.
  - For adult beneficiaries with locally advanced or metastatic urothelial carcinoma who have:
    - Disease progression during or following platinum-containing chemotherapy
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
- **Colorectal cancer**
  - For adult beneficiaries with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient dMMR metastatic colorectal cancer (CRC), following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).
  - For adult beneficiaries with MSI-H or dMMR metastatic CRC that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.
    - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of MSI-H or dMMR metastatic CRC.
- **Hepatocellular carcinoma (HCC)**
  - For adult beneficiaries with HCC who were previously treated with sorafenib and following combination treatment with intravenous nivolumab and ipilimumab.
    - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of HCC.
- **Esophageal cancer**
  - For treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult beneficiaries who have received neoadjuvant chemoradiotherapy

- Used in combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) with tumors expressing PD-L1 (≥ 1).
  - **Limitations of use**: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of beneficiaries with unresectable advanced or metastatic ESCC.
- For adult beneficiaries with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy.

- **Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**
  - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy for adult beneficiaries with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma with tumors expressing PD-L1 (≥ 1).

APPROVAL DURATION

Approval is for 6 months and may be renewed, unless otherwise noted.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding positively to therapy (e.g., labs, signs/symptom reduction)
- No unacceptable toxicity to the drug

BILLING/CODING INFORMATION

Applicable service codes:

- J9289 – Injection, nivolumab, 2 mg and hyaluronidase-nvhy.

OPDUALAG (NIVOLUMAB/RELATLIMAB-RMBW)

Updated: 04/25/2024

INDICATIONS

Opdualag is indicated for treatment of:

- **Unresectable or metastatic melanoma**

CLINICAL CRITERIA

- The beneficiary is 12 years of age or older and weighs at least 40 kg (88 lbs).
- Opdualag is prescribed by or in consultation with an oncologist.
- The beneficiary has a diagnosis of one of the following:
  - Unresectable melanoma
  - Metastatic melanoma

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation [HSCT], severe immune-mediated adverse reactions, such as pneumonitis, colitis, hepatitis, nephritis/renal dysfunction, myocarditis, etc.)
- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- **Notes:**
  - Beneficiaries responding to therapy who relapse ≥ 6 months after discontinuation due to duration (e.g., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
  - Beneficiaries who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
  - Beneficiaries 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.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9298 – Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg

OPTUNE (TUMOR TREATING FIELD DELIVERY SYSTEM)

Updated: 04/25/2024

INDICATIONS

Optune is intended as a treatment for adults 22 years of age or older with histologically confirmed **glioblastoma multiforme (GBM)**.

Optune with temozolomide is indicated for the treatment of adults with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and following completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receipt of chemotherapy. The device is intended to be used as a monotherapy and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

CLINICAL CRITERIA

- For treatment of newly diagnosed supratentorial glioblastoma in beneficiaries 22 years of age or older
- For initial treatment with debulking surgery or biopsy, followed by completion of radiation therapy together with concomitant temozolomide chemotherapy; **AND**
  - The beneficiary has a Karnofsky Performance Status (KPS)* score of > 60; **AND**
  - The beneficiary or caregiver has been trained and is willing and able to apply the device daily; **AND**
  - The beneficiary is willing to wear the device for at least 18 hours daily.
- When all of the above criteria are met, consider an initial 3 months of electric TTFields therapy.

*The Karnofsky Performance Scale Index is an assessment tool for functional impairment. The lower the Karnofsky score, the worse the likelihood of survival. 60% indicates that the beneficiary requires occasional assistance but is able to care for most personal needs.

APPROVAL DURATION

Initial approval for 3 months of electric TTF therapy

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Evidence of no disease progression as documented by MRI imaging done at a minimum of every 2-4 months. This includes a completed MRI scan with report submitted as part of any request for continuation of TTF treatment; **AND**
- KPS score of > 60; **AND**
- Documentation that the beneficiary or caregiver has been applying the device daily; **AND**
- Documentation that the beneficiary has been wearing the device at least 18 hours daily

BILLING/CODING INFORMATION

The NCCN has included Optune as a category 2B treatment option for recurrent GBM since 2015. There are several major private insurance companies that are now covering the Optune device under the following HCPCS codes:

- E0766 – Electrical stimulation device used for cancer treatment, includes all accessories, any type
- A4555 – Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
- J8700 – Temozolomide, oral, 5 mg
- J9328 – Injection temozolomide, 1 mg

ORENCIA (ABATACEPT)

Updated: 04/25/2024

INDICATIONS

- **Rheumatoid arthritis (RA)**
- **Polyarticular juvenile idiopathic arthritis (JIA)**
- **Psoriatic arthritis**
- **Acute graft versus host disease (aGVHD)**

CLINICAL CRITERIA

- The beneficiary has been screened for latent TB infection prior to initiating therapy.
  - Beneficiaries who test positive should be treated prior to initiating Orencia.
- The beneficiary does not have an active infection.

Rheumatoid arthritis (RA)

- The beneficiary must be 18 years of age or older.
- The beneficiary has clinically diagnosed moderate to severe rheumatoid arthritis.
- The beneficiary has had an inadequate response, intolerance, or contraindication to a non-biologic disease modifying anti-rheumatic (DMARD) (e.g., methotrexate, sulfasalazine, azathioprine).
- The drug is used as a monotherapy or in combination with a non-biologic DMARD.
- The requesting physician is a rheumatologist.
- The beneficiary is not receiving Orencia in combination with **either** of the following:
  - A biologic disease modifying anti-rheumatic (DMARD) agent (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
  - A janus kinase inhibitor (e.g., Xeljanz [tofacitinib])

Juvenile idiopathic arthritis (JIA)

- The beneficiary is 2 years of age or older.
- The beneficiary has clinically diagnosed moderate to severe active polyarticular juvenile idiopathic arthritis.
- The beneficiary has had an inadequate response, intolerance, or contraindication to a non-biologic DMARD.
- The drug is used as monotherapy or in combination with methotrexate.
- The requesting physician is a rheumatologist.
- The beneficiary is not receiving Orencia in combination with **either** of the following:
  - A biologic DMARD agent (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
  - A Janus kinase inhibitor (e.g., Xeljanz [tofacitinib])

Psoriatic arthritis

- The beneficiary is 2 years of age or older.
- The beneficiary has clinically diagnosed active psoriatic arthritis.

- The beneficiary has had an inadequate response, intolerance, or contraindication to a non-biologic DMARD
- The beneficiary is not receiving Orencia in combination with **any** of the following:
  - A biologic DMARD agent (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
  - A Janus kinase inhibitor (e.g., Xeljanz [tofacitinib])
  - Phosphodiesterase 4 (PDE4) inhibitor (e.g., Otezla [apremilast])

Prophylaxis of acute graft versus host disease

- The beneficiary is 2 years of age or older.
- The beneficiary is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.
- The drug is used in combination with a calcineurin inhibitor and methotrexate.
- The beneficiary is not receiving Orencia in combination with other immunosuppressives (e.g., biologic disease-modifying antirheumatic drugs [bDMARDS], Janus kinase inhibitors)

APPROVAL DURATION

Authorization is for 6 months

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of positive clinical response to Orencia therapy
- The beneficiary is not receiving Orencia in combination with any of the following:
  - A biologic disease modifying anti-rheumatic (DMARD) agent (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
  - A Janus kinase inhibitor (e.g., Xeljanz [tofacitinib])
  - A phosphodiesterase 4 (PDE4) inhibitor (e.g., Otezla [apremilast]) if used for psoriatic arthritis

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0129 – Injection, Abatacept, 10 mg; 1 billable unit = 10 mg

OXLUMO (LUMASIRAN)

Updated: 11/26/2025

INDICATIONS

Oxlumo (lumasiran) is indicated for **primary hyperoxaluria Type 1 (PH1)** to lower urinary and plasma oxalate levels in pediatric and adult beneficiaries.

CLINICAL CRITERIA

- Oxlumo is prescribed by or in consultation with a residency-trained nephrologist or urologist.
- The beneficiary has a diagnosis of PH1 confirmed by either of the following:
  - Molecular genetic test results demonstrating a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene; **OR**
  - Liver enzyme analysis results demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity; **AND**
- The beneficiary has elevated urine oxalate excretion > 0.5 mmol/24 hours/1.73 m^2 with the absence of secondary sources of oxalate.
- The beneficiary has tried high dose pyridoxine and did not obtain an adequate response (defined as having had < 30% reduction in urinary or plasma oxalate concentration).
- The provider must submit documentation of previous treatments and results.

EXCLUSIONS

- **Primary hyperoxaluria Type 2 (PH2).** Oxlumo is not expected to be effective for the treatment of PH2 because its mechanism of action does not affect the metabolic pathways causing hyperoxaluria in PH2.
- **Primary hyperoxaluria Type 3 (PH3).** Oxlumo is not expected to be effective for the treatment of PH3 because its mechanism of action does not affect the metabolic pathways causing hyperoxaluria in PH3.
- **Concurrent use of Oxlumo with Rivfloza (nedosiran subcutaneous injection).** Oxlumo is another small interfering RNA agent and should not be used with Rivfloza.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary must have documentation that there is clinically significant reduction in urinary oxalate excretion, spot urinary oxalate, creatinine ratio, or plasma oxalate levels with Oxlumo therapy.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0224 – Injection, lumasiran, 0.5 mg (Oxlumo)

OZURDEX (DEXAMETHASONE INTRAVITREAL IMPLANT)

Updated: 04/25/2024

INDICATIONS

Ozurdex is indicated for treatment of:

- **Macular edema** following branch or central retinal vein occlusion
- **Non-infectious uveitis** affecting the posterior segment of the eye
- **Diabetic macular edema**

CLINICAL CRITERIA

- The drug is prescribed by or in consultation with an ophthalmologist.
- The beneficiary has a diagnosis of macular edema, non-infectious uveitis, or diabetic macular edema.

EXCLUSIONS/CONTRAINDICATIONS

- Active ocular or periocular infection
- Glaucoma
- Torn or ruptured posterior lens capsule
- Hypersensitivity

APPROVAL DURATION

Authorization is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary continues to meet initial approval criteria.
- The beneficiary continues to have need for therapy based on FDA prescribing indications.
- The provider has documentated the beneficiary's benefit from the drug and a long-term plan for continued treatment.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7312 – Injection, dexamethasone, intravitreal implant, 0.1 mg

PADCEV (ENFORTUMAB VEDOTIN-EJFV)

Updated: 05/16/2024

INDICATIONS

Urothelial carcinoma

CLINICAL CRITERIA

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary is an adult 18 years of age or older.
- The drug may be used as a single agent for the treatment of locally advanced or metastatic urothelial cancer in adult beneficiaries who:
  - Have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand (PD-L1) inhibitor and platinum-containing chemotherapy; **OR**
  - Are ineligible for cisplatin-containing chemotherapy and have received one or more prior lines of therapy.
- The drug may be used in combination with pembrolizumab (Keytruda) in adult beneficiaries with locally advanced or metastatic urothelial cancer.
- The beneficiary does not have uncontrolled diabetes mellitus (i.e., baseline serum glucose > 250 mg/dL or hemoglobin A1C ≥ 8%).
- The beneficiary does not have pre-existing peripheral neuropathy.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., severe hyperglycemia or diabetic ketoacidosis, severe peripheral neuropathy, ocular disorders [including vision changes], severe skin reactions, including Steven Johnson syndrome, or toxic epidermal necrolysis)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9177 – Injection, enfortumab vedotin-ejfv, 0.25 mg: 1 billable unit = 0.25 mg

PARSABIV (ETELCALCETIDE)

Updated: 10/10/2024

INDICATIONS

Parsabiv is indicated for treatment of:

- **Secondary hyperparathyroidism (HPT) in adults with chronic kidney disease (CKD) on hemodialysis**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- The beneficiary has secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD)
- The beneficiary **must** be on hemodialysis
- The beneficiary must have intact parathyroid hormone (iPTH) level > 300 pg/mL
- The beneficiary has serum calcium level (corrected for albumin) ≥ 7.5 mg/dL
- The beneficiary must not be taking another calcium-sensing receptor agonist (e.g., Sensipar, Rocaltrol, Hectorol, Zemplar)

EXCLUSIONS

- Parsabiv has not been studied and is not recommended in beneficiaries with parathyroid carcinoma, primary hyperparathyroidism, or those with CKD who are not on hemodialysis.
- Beneficiaries with known hypersensitivity to etelcalcetide (Parsabiv) or any of its excipients.

APPROVAL DURATION

Initial authorization is for 6 months

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding positively to therapy, as evidenced by a decrease in iPTH

BILLING/CODING INFORMATION

J0606 – Injection, etelcalcetide, 0.1 mg; 0.1 mg = 1 billable unit

PEMETREXED DISODIUM (ALIMTA, PEMFEXY) IV

Updated: 08/09/2024

INDICATIONS

Pemetrexed is FDA-indicated for:

- **Non-squamous non-small cell lung cancer (NSCLC)**
- **Malignant pleural mesothelioma**

CLINICAL CRITERIA

- **Non-squamous, non-small cell lung cancer (NSCLC)**
  - The beneficiary must be 18 years of age or older
  - The drug is used in combination with pembrolizumab (Keytruda) and platinum chemotherapy for the initial treatment of beneficiaries with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
  - The drug is used in combination with a cisplatin (or carboplatin as a well-recognized off-label substitution) for the initial treatment of beneficiaries with locally advanced or metastatic non-squamous NSCLC
  - The drug is used as a single agent for the maintenance treatment of locally advanced or metastatic non-squamous NSCLS in beneficiaries whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
  - The drug is used as a single agent for the treatment of beneficiaries with recurrent metastatic non-squamous NSCLC after prior chemotherapy.
- **Malignant pleural mesothelioma**
  - The beneficiary must be 18 years of age or older.
  - The drug is used in combination with a cisplatin- or carboplatin-based regimen.
  - The drug is used as single-agent therapy.
  - The drug must be prescribed by an oncologist or hematologist.

OFF-LABEL USE RECOMMENDATIONS

- **Cervical Cancer**
  - The beneficiary has recurrent, advanced, or metastatic cervical cancer

EXCLUSIONS

- Pemetrexed is not indicated for the treatment of beneficiaries with the following:
  - Squamous cell, non-small cell lung cancer

APPROVAL DURATION

Approval will be for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of clinical benefit from pemetrexed

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., bone marrow suppression, renal impairment, bullous and exfoliative skin toxicity, interstitial pneumonitis)

BILLING/CODING INFORMATION

J-code:

- J9305 – Injection, pemetrexed, 10 mg; 1 billable unit = 10 mg
- J9304 – Injection, pemetrexed (pemfexy), 10 mg

PERJETA (PERTUZUMAB), POHERDY (PERTUZUMAB-DPZB)

Updated: 11/14/2025

INDICATIONS

Perjeta (pertuzumab) and Poherdy (pertuzumab-dpzb) are indicated for treatment of:

- **Breast cancer (FDA)**
- **Colon cancer (NCCN)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment.
- The drug is prescribed by an oncologist.

Breast cancer

- The drug is used in combination with trastuzumab and docetaxel for treatment of HER2-positive metastatic breast cancer in beneficiaries who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- The drug is used in combination with trastuzumab and chemotherapy as:
  - Neoadjuvant treatment of beneficiaries with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
  - Adjuvant treatment of beneficiaries with HER2-positive early breast cancer at high risk of recurrence.

FDA WARNING

- **Left ventricular dysfunction**: Perjeta can result in subclinical and clinical cardiac failure manifesting as decreased LVEF and CHF. Evaluate cardiac function prior to and during treatment. Discontinue Perjeta treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-fetal toxicity**: Exposure to Perjeta can result in embryo-fetal death and birth defects. Advise beneficiaries of these risks and the need for effective contraception.

NCCN RECOMMENDATIONS

Colon cancer (CRC)

- The drug is used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; **AND**
  - Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CapeOX within the past 12 months; **AND**
  - Prior to approval of pertuzumab, the beneficiary must demonstrate an adequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance; **OR**
- The drug is used as subsequent therapy for progression of advanced or metastatic disease, **AND**
  - The beneficiary has not previously received HER2-targeted therapy, **AND**

- Prior to approval of pertuzumab, the beneficiary must demonstrate an adequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance.

Appendiceal adenocarcinoma – colon cancer

- Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; AND
- The beneficiary has not previously received HER2-targeted therapy; **AND**
- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
- The beneficiary must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of pertuzumab.

Head and neck cancers

- The beneficiary has salivary gland tumors; **AND**
- Used in combination with trastuzumab; **AND**
- The beneficiary has recurrent disease with one of the following:
  - Distant metastases
  - Unresectable locoregional recurrence with prior radiation therapy (RT)
  - Unresectable second primary with prior RT; **AND**
- The beneficiary must demonstrate an inadequate response to trastuzumab/docetaxel, unless there is a contraindication or intolerance, prior to approval of pertuzumab

APPROVAL DURATION

Approval is for 6 months and may be renewed (unless otherwise specified).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Left ventricular ejection fraction (LVEF) is within normal limits
- Use for adjuvant OR neoadjuvant breast cancer treatment is limited to up to a year of treatment (total of 18 cycles)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9306 – Injection, pertuzumab, 1 mg; 1 mg = 1 billable unit

PLUVICTO (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN)

Updated: 03/31/2025

INDICATIONS

Pluvicto is indicated for the treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) in adult beneficiaries who have been treated with androgen receptor pathway inhibition and are considered appropriate to delay taxane-based chemotherapy.

CLINICAL CRITERIA

- The beneficiary has metastatic castration-resistant prostate cancer (mCRPC).
- The beneficiary has at least one prostate-specific membrane antigen (PSMA)-positive lesion or predominately PSMA-positive disease.
- The beneficiary has previously been treated with an androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.) and is considered appropriate to delay taxane-based chemotherapy.
- The beneficiary has had a bilateral orchiectomy or will be using Pluvicto in combination with a GnRH agonist or degarelix (Firmagon).
- The beneficiary has a current ECOG performance status of 0 to 2.

APPROVAL DURATION

Approval is for 6 months (4 doses) and may be renewed for 2 additional doses. The total number of doses authorized cannot exceed 6 doses.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Continuation of Pluvicto therapy (up to 6 total doses) is allowed in absence of unacceptable toxicity from the drug and disease progression while on the current regimen.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- A9607 – Radiopharmaceutical, therapeutic, not otherwise classified.

POLIVY (POLATUZUMAB VEDOTIN-PIIQ)

Updated: 05/09/2024

INDICATIONS

Diffuse large B-cell lymphoma

- Polivy is indicated in combination with bendamustine (Bendeka) and a rituximab product for the treatment of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, in adult beneficiaries who have received at least two prior therapies.

CLINICAL CRITERIA

Diffuse large B-cell lymphoma (DLBCL)

- The drug is used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified or high-grade B-cell lymphoma in adult beneficiaries who have who have an International Prognostic Index score of 2 or greater.
- The drug may also be used in combination with bendamustine and a rituximab product for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, in adult beneficiaries who have received at least two prior therapies.
- The beneficiary will receive prophylaxis for Pneumocystis jiroveci pneumonia and herpesvirus

NCCN RECOMMENDED USES (OFF-LABEL)

- Polivy is prescribed as a single agent or in combination with bendamustine or a rituximab product.
- Polivy may be prescribed to treat follicular lymphoma (FL), mantle cell lymphoma, or post-transplant lymphoproliferative disorder (B-cell type).
- The dose is prescribed within the FDA maximum for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for relevant off-label uses.

APPROVAL DURATION

Approval is for six months (up to 6 cycles of therapy) and may NOT be renewed

RENEWAL/REAUTHORIZATION

Cannot be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9309 – Injection, polatuzumab vedotin-piiq, 1 mg

PROVENGE (SIPULEUCEL-T)

Updated: 10/10/2024

INDICATIONS

Provenge is indicated for treatment of:

- **Prostate cancer**

CLINICAL CRITERIA

Prostate cancer

- The drug must be prescribed by a hematologist or oncologist.
- The beneficiary has castration-resistant (hormone refractory) metastatic disease.
- The beneficiary has no solid organ metastases (e.g., liver, lung, brain).
- The drug must NOT be used in combination with chemotherapy or immunosuppressive therapy.
- The beneficiary is asymptomatic or minimally symptomatic.
- The beneficiary has not previously received therapy with sipuleucel-T.

EXCLUSIONS

- The beneficiary has visceral disease or metastases in castration-resistant prostate cancer.
- The beneficiary is receiving concomitant chemotherapy or immunosuppressive therapy.

APPROVAL DURATION

Approval is provided for 3 doses only

RENEWAL/REAUTHORIZATION

Cannot be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Q2043 – Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP and GM-CSF, including leukapheresis and all other preparatory procedures, per infusion
  - 1 billable unit = 1 dose (Code Price is per 250 mL)

PYLARIFY (PIFLUFOLASTAT F 18)

Updated: 10/10/2024

INDICATIONS

Pylarify is indicated for:

- **Positron emission tomography (PET) of prostate-specific membrane antigen (PMSA) positive lesions in men with prostate cancer**

CLINICAL CRITERIA

- For treatment of suspected metastasis in adult male beneficiaries who are candidates for initial definitive therapy.
- For treatment of suspected recurrence in adult male beneficiaries based on elevated serum prostate-specific antigen (PSA) level.

APPROVAL DURATION

Pylarify is administered as a bolus intravenous injection from a single-dose syringe. Approval is limited to one single-dose syringe.

RENEWAL/REAUTHORIZATION

May not be renewed.

BILLING/CODING INFORMATION

- A9597 – Positron emission tomography radiopharmaceutical, diagnostic for tumor ID, NOC Radiopharmaceutical, diagnostic, not otherwise classified.
- **Note**: As NOC codes are not drug specific, bill as “1” unit

RADICAVA (EDARAVONE)

Updated: 02/12/2024

INDICATIONS

Radicava is indicated for treatment of:

- **Amyotrophic lateral sclerosis (ALS)**

CLINICAL CRITERIA

Amyotrophic lateral sclerosis (ALS)

- The beneficiary has a diagnosis of clinically definite or probable ALS based on El Escorial revised criteria or Awaji criteria.
- The beneficiary has a disease duration of 2 years or less.
- The beneficiary has a percent-predicted forced vital capacity (%FVC) ≥ 80%
- The beneficiary has baseline documentation of retained functionality for most activities of daily living (e.g., a score of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised [ALSFRS-R])

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALDFRS-R (the beneficiary has not experienced rapid disease progression while on therapy)
- The beneficiary does not have a cumulative score on the ASLFRS-R of ≤ 3.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1301 − Injection, edaravone, 1 mg; 1 billable unit = 1 mg

REBLOZYL (LUSPATERCEPT-AAMT)

Updated: 03/28/2025

INDICATIONS

Reblozyl is indicated for treatment of:

- **Beta thalassemia**
- **Myelodysplastic syndrome**

CLINICAL CRITERIA

Beta thalassemia

- The beneficiary has a diagnosis of red blood cell transfusion (RBC) dependent beta thalassemia.
- The drug is prescribed by a hematologist or other specialist with expertise in the diagnosis and management of beta thalassemia.
- The provider has ruled out or addressed other causes of anemia (e.g., gastrointestinal bleeding, hemolysis, renal disease, nutritional deficiency, etc.).
- The beneficiary is not a candidate for sibling-matched hematopoietic stem-cell transplantation (HSCT).
- **Note**: Approval will be considered on a case-by-case basis for beneficiaries with high transfusion burden and symptomatic iron overload, history of alloimmunization, or history of transfusion reactions.
- **Limitation of Use**: Reblozyl is not indicated for use as a substitute for RBC transfusions in beneficiaries who require immediate correction of anemia.

Myelodysplastic syndrome

- The drug is prescribed by a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndrome.
- The adult beneficiary has one of the following:
  - Anemia without previous erythropoiesis simulating agent use (ESA-naïve); **AND**
    - With very low- to intermediate-risk myelodysplastic syndrome (MDS); **AND**
    - The beneficiary may require regular red blood cell transfusions; **OR**
  - Anemia failing an erythropoiesis stimulating agent requiring 2 or more RBC units over 8 weeks with one of the following:
    - Very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS); **OR**
    - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis.
- The provider has ruled out or addressed other causes of anemia (e.g., gastrointestinal bleeding, hemolysis, renal disease, nutritional deficiency, etc.)
- The beneficiary has documentation of hemoglobin < 10 g/dL and documentation that they required 2 or more red blood cell units in the prior 8 weeks.
- **Limitation of Use**: Reblozyl is not indicated for use as a substitute for RBC transfusions in beneficiaries who require immediate correction of anemia.

EXCLUSIONS

- Alpha thalassemia
- Beta thalassemia in pediatric beneficiaries
- Non-transfusion-dependent thalassemia (NTDT) beneficiaries
- Myeloproliferative neoplasm-associated myelofibrosis
- Sickle beta thalassemia (hemoglobin S [HbS]/beta thalassemia)
- Severe iron overload
  - **Note**: The beneficiary may be eligible for approval of Reblozyl after assessment and determination that they do not have symptomatic iron overload.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is experiencing disease response, as evidenced by a decrease in the number of RBC transfusions of ≥ 20% versus baseline.
- The beneficiary experienced a mean hemoglobin increase from baseline of ≥ 1.5 g/dL.
- The beneficiary has not experienced unacceptable toxicity from the drug (e.g., thromboembolic events, severe hypertension, etc.)
- Per FDA label: The drug should be discontinued if the beneficiary does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0896 – Injection, luspatercept-aamt, 0.25 mg: 1 billable unit = 0.25 mg

REBYOTA (FECAL MICROBIOTA, LIVE – JSLM)

Updated: 10/16/2025

INDICATIONS

Rebyota is indicated for the prevention of recurrence of:

- ***Clostridioides difficile* infection (CDI)**
  - **Note**: Rebyota is **not** indicated for **treatment** of CDI

CLINICAL CRITERIA

- The beneficiary is ≥ 18 years of age.
- Rebyota is being utilized for recurrent or life threatening clostridioides difficile infection (CDI) in beneficiaries under the care of a fellowship trained GI specialist
- Treatment is being utilized for prevention of additional CDI infections (contraindicated until the beneficiary has completed an approved treatment regimen).
- Treatment will be administered within 24 to 72 hours of completing antibiotic treatment for current clostridiodes difficile infection.
- The beneficiary has not previously received Rebyota, Vowst, or prior fecal microbiota transplants within the last 2 years.
- The beneficiary has failed therapy with pulsed dose fidaxomicin and bezlotoxumab (Zinplava).

APPROVAL DURATION

Approval is for one dose.

RENEWAL/REAUTHORIZATION

Not renewable/reauthorized

RECOMMENDED DOSING

One 150 mL treatment

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1440 – Fecal microbiota, live – jslm, 1 mL

RECOVI (ELAPEGADEMASE-LVLR)

Updated: 09/04/2025

INDICATIONS

Recovi is indicated for the treatment of:

- **Adenosine deaminase severe combined immune deficiency (ADA-SCID)**

CLINICAL CRITERIA

- Recovi is prescribed by an immunologist, hematologist, oncologist, or physician who specializes in the treatment of immune system disorders.
- The beneficiary has a diagnosis of severe combined immunodeficiency disease (ADA-SCID) with a definitive diagnosis of adenosine deaminase confirmed by any of the following:
  - Deficiency or absence of adenosine deaminase (ADA) in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus sample
  - Increase in either deoxyadenosine triphosphate (dATP) levels or in total deoxyadenosine nucleotides (dAXP) in erythrocytes
  - Decrease in ATP concentration in erythrocytes
  - Molecular genetic confirmation of mutations in both alleles of the ADA1 gene
  - Positive screening by T-cell receptor excision circles (TRECs)
- Recovi will be used only until definitive therapy with hematopoietic stem cell transplantation (HSCT), or if the beneficiary is not a suitable candidate or has previously failed HSCT.
- Baseline values for trough plasma ADA activity, red blood cell deoxyadenosine triphosphate (dATP), trough deoxyadenosine nucleotide (dAXP), or total lymphocyte counts have been obtained.
- The beneficiary does not have severe thrombocytopenia (< 50,000/microL).

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease stability or improvement, as indicated by one or more of the following:
  - Normalization or increase in plasma ADA activity (target trough level $\geq$ 15 mmol/hr/L)
  - Red blood cell dATP level decreased (target $\leq$ 0.005 to 0.015 mmol/L)
  - Improvement in immune function with diminished frequency or complications of infection, as evidenced in improvement in the ability to produce antibodies
  - Improvement in red blood cell dAXP levels (target trough level $\leq$ 0.02 mmol/L)
- Absence of unacceptable toxicity from Recovi (e.g., severe thrombocytopenia)

RECOMMENDED DOSING (PER FDA PRESCRIBING INDICATIONS)

- For beneficiaries transitioning from Adagen to Revcovi: The starting dose of Revcovi is 0.2 mg/kg weekly, intramuscularly.

- For Adagen-naïve beneficiaries: The starting dose of Revcovi is 0.4 mg/kg weekly based on ideal body weight or actual weight, whichever is greater, divided into two doses (0.2 mg/kg twice a week), intramuscularly.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Revcovi - Unclassified biologics; 1 mg = 1 billable unit.

RELIZORB (IMMOBILIZED LIPASE CARTRIDGE)

Updated: 11/04/2024

INDICATIONS

Relizorb is indicated for:

- Use in adult and pediatric beneficiaries 2 years of age or older to hydrolyze fats in enteral formula

CLINICAL CRITERIA

- For adult and pediatric beneficiaries 2 years of age or older
- The beneficiary has a diagnosis supporting the use of enteral nutrition for the management of malabsorption and maldigestion of an oral diet.
  - Examples of disease states associated with malabsorption/maldigestion include exocrine pancreatic insufficiency (EPI), inflammatory bowel disease (IBD), chronic pancreatitis (CP), advanced liver disease, cystic fibrosis (CF), and short bowel syndrome (SBS).
- The beneficiary has clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by:
  - In adults, one of the following:
    - Showing involuntary or acute weight loss of ≥ 10 percent of usual body weight during a 3 to 6-month period; **OR**
    - Body mass index (BMI) below 18.5 kg/m^2
  - In children, one of the following:
    - No weight gain or abnormally slow rate of gain for 3 months; **OR**
    - Weight for height below the 10th percentile; **OR**
    - Abnormal laboratory tests pertinent to the diagnosis and risk factors for actual or potential malnutrition have been identified
- Enteral nutrition is indicated as the primary source of nutritional support essential for the management factors that impair digestion or malabsorption.
- The risk factors for actual or potential malnutrition have been identified and documented. Risk factors may include the following:
  - Anatomic structures of the gastrointestinal tract that impair digestion and absorption
  - Neurological disorders that impair swallowing or chewing
  - Diagnosis of inborn errors of metabolism that require food products modified to be low in protein (e.g., phenylketonuria [PKU], tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria)
  - Intolerance or allergy to standard milk-based or soy formulas (e.g., diarrhea, bloody stool, excessive gas, abdominal pain, severe GERD, severe eczema) that have improved with a trial of specialized formula and for which such formula is needed for adequate nutrition
  - Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds
  - Treatment with anti-nutrient or catabolic properties (e.g., anti-tumor treatments, corticosteroids, immunosuppressant, stimulant medications)

- Increased metabolic or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake or retention
- A failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake or retention

EXCLUSIONS

- The beneficiary is underweight but has the ability to meet nutritional needs through the use of regular formula or food consumption
- The beneficiary has constipation, mild gastroesophageal reflux disease (GERD) that does not require pharmacologic treatment, mild eczema that only requires topical corticosteroids, fussiness, colic, and gassiness without the indications of malabsorption or nutritional risk.
- Enteral products are used as supplements to a normal or regular diet in beneficiaries showing no clinical indicators or nutritional risk.
- Enteral nutrition products used for dieting or weight loss program

APPROVAL DURATION

Initial authorization is approved for 6 months

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is continuing on enteral tube feedings
- The beneficiary has documentation of no decrease in BMI while maintained on enteral feedings and Relizorb digestive enzyme cartridge therapy

BILLING/CODING INFORMATION

Applicable Procedure Codes

- B4105 – In-line cartridge containing digestive enzyme(s) for enteral feeding, 1 cartridge

RETACRIT (EPOETIN ALFA-EPBX)

Updated: 10/08/2024

INDICATIONS

Retacrit is indicated for treatment of **anemia** due to:

- Chronic kidney disease (CKD) in beneficiaries on dialysis and beneficiaries not on dialysis
- Zidovudine (also known as azidothymidine [AZT] – an antiretroviral medication)
- Chemotherapy treatment
  - **Note**: Only for palliative chemotherapy. See exclusion below for curative chemotherapy.
- Reduction of allogeneic RBC transfusions in beneficiaries undergoing elective, non-cardiac, non-vascular surgery

CLINICAL CRITERIA

Note: Lab values should be obtained within 30 days of the date of administration.

- For chronic kidney disease (CKD):
  - The beneficiary has anemia due to chronic kidney disease (CKD), including beneficiaries on dialysis and beneficiaries not on dialysis.
- For zidovudine in beneficiaries with HIV-infection:
- The beneficiary is experiencing effects of concomitant myelosuppressive chemotherapy, and upon initiation, there are a minimum of two additional months of planned chemotherapy.
- The beneficiary is undergoing elective, non-cardiac, non-vascular surgery.
  - The beneficiary has hemoglobin (Hb) between 10 g/dL and 13 g/dL or hematocrit (Hct) between 30% and 39%; **AND**
  - The beneficiary is at high risk of blood loss from surgery that is elective, non-cardiac, and non-vascular; **AND**
  - The beneficiary is unwilling or unable to participate in an autologous blood donation program prior to surgery.

COMPENDIA RECOMMENDED INDICATIONS

For anemia due to myelodysplastic syndrome (MDS):

- The beneficiary has symptomatic anemia.
- The beneficiary has lower risk disease (defined as IPPS [Low and Intermediate-1]).
  - The drug is used as a single agent for del(5q) mutation (excluding use in beneficiaries with cytogenetic abnormality involving chromosome 7); **OR**
- The beneficiary has lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate]); **AND**
  - The beneficiary does not have del(5q) mutation,
    - The beneficiary has a serum erythropoietin (EPO) ≤ 500 mU/mL; **AND**
      - The beneficiary has ring sideroblasts < 15% (or < 5% with an SF3B1 mutation); **AND**
        - The drug is used as a single agent; **OR**

        - The drug is used in combination with either lenalidomide or a granulocyte-colony stimulating factor (G-CSF) following no response (despite adequate iron stores) or erythroid response followed by loss of response to an erythropoiesis-stimulating agent (ESA) alone.
    - The beneficiary has ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation); **AND**
        - The drug is used as a single agent; **OR**
        - The drug is used in combination with a G-CSF.

EXCLUSIONS

Retacrit may not be used concomitantly with other erythropoiesis stimulating agents (Epogen, Procrit, Aranesp and Mircera).

Retacrit is not indicated for use:

- In beneficiaries with cancer who are receiving hormonal agent, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
- In beneficiaries with cancer who are receiving myelosuppressive chemotherapy when the anticipated outcome is cure
- In beneficiaries with cancer who are receiving myelosuppressive chemotherapy and in whom the anemia can be managed by transfusion
- In beneficiaries scheduled for surgery who are willing to donate autologous blood
- In beneficiaries undergoing cardiac or vascular surgery
- As a substitute for RBC transfusions in beneficiaries who require immediate correction of anemia

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by improvement in anemia compared to pre-treatment baseline.
- Absence of unacceptable toxicity from the drug, (e.g., severe cardiovascular events [stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.], uncontrolled hypertension, increased risk of tumor progression/recurrence in beneficiaries with cancer)

Anemia due to myelodysplastic syndrome (MDS)

- Hemoglobin (Hb) < 12 g/dL or hematocrit (Hct) < 36%

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Q5105 Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units
- Q5106 Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units

RETISERT (FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT)

Updated: 10/10/2024

INDICATIONS

Retisert is indicated for treatment of:

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

CLINICAL CRITERIA

- The beneficiary is 12 years of age or older
- The beneficiary must have chronic non-infectious uveitis affecting the posterior segment of the eye
- The drug must be prescribed by a retinal specialist
- The beneficiary has failed (e.g., recurrent uveitis despite use of traditional therapy) or was intolerant to traditional therapy including steroids (systems, periocular injection)
- The beneficiary has failed to respond to a trial (at least a 28-day course) of immunosuppressants (cyclosporine, azathioprine, methotrexate)

EXCLUSIONS

- The beneficiary has a viral disease of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella
- The beneficiary has mycobacterial infections of the eye
- The beneficiary has fungal diseases of ocular structures
- The beneficiary has any contraindications to the use of Retisert

APPROVAL DURATION

Authorization is limited to one implant into the affected eye. Subsequent authorization (up to 6 months) will be based on documentation of efficacy.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation supporting improvement of condition

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J7311 – intravitreal implant, 0.59 mg

RITUXIMAB (RITUXAN, TRUXIMA, RUXIENCE, RIABNI), (RITUXAN HYCELA)

Updated: 01/30/2025

INDICATIONS

Rituximab (Rituxan and biosimilars) are FDA-indicated for:

- **Adult non-Hodgkin lymphoma (NHL)**
- **Pediatric mature B-cell NHL and mature B-cell acute leukemia (B-AL)**
- **Chronic lymphocytic leukemia (CLL)**
- **Rheumatoid arthritis (RA)**
- **Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) (collectively known as ANCA-associated Vasculitis [AAV])**
- **Pemphigus vulgaris (PV)**
- **Diffuse large B-cell lymphoma**

Rituxan Hycela (rituximab and hyaluronidase human) is FDA-indicated for:

- **Follicular lymphoma (FL)**
- **Diffuse large B-cell lymphoma (DLBCL)**
- **Chronic lymphocytic leukemia (CLL)**

Limitations of use: Initiate treatment with Rituxan Hycela only after the beneficiary has received at least one full dose of a rituximab product by intravenous infusion.

CLINICAL CRITERIA

Note: The beneficiary must be screened for HBV infection (e.g., HBsAg and anti-HBc) prior to initiating therapy

Adult beneficiaries with non-Hodgkin lymphoma (NHL)

- The beneficiary must be 18 years of age or older
- The drug is used as a single agent for relapsed or refractory, low grade or follicular NHL
- The drug is used as single-agent maintenance therapy in combination with first line chemotherapy for previously untreated follicular NHL in beneficiaries achieving a complete or partial response to a rituximab product
- The drug is used as a single agent after first line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy for non-progressing (including stable disease), low-grade NHL
- The drug is used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens for previously untreated diffuse large B-cell NHL
- The drug must be prescribed by or in consultation with an oncologist or hematologist

Pediatric beneficiaries with mature B-cell NHL and mature B-cell acute leukemia

- The beneficiary is 6 months of age or older

- The drug is used in combination with chemotherapy for previously untreated, advanced stage diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL)

Chronic lymphocytic leukemia (CLL)

- The beneficiary must be 18 years of age or older
- The drug is used for previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide
- The drug must be prescribed by or in consultation with an oncologist or hematologist

Rheumatoid arthritis (RA)

- The beneficiary must be 18 years or older
- The beneficiary must be clinically diagnosed with moderate to severe, active disease
- The drug must be prescribed by a rheumatologist
- The beneficiary has documentation indicating that the drug is being used concurrently with methotrexate unless they have a contraindication or intolerance
- The beneficiary has documentation that they have tried and failed one oral disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.)
- The beneficiary has documentation that they have tried and failed or are intolerant to one or more tumor necrosis factor (TNF) inhibitors (e.g., Enbrel, Humira, and Remicade)
- The beneficiary has not had treatment with rituximab in the previous 4 months

Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) (grouped as ANCA-associated vasculitis [AAV])

- The beneficiary is at least 2 years of age
- The drug is used in combination with glucocorticoids (e.g., prednisone, methylprednisolone, etc.)

Pemphigus vulgaris (PV)

- The beneficiary must be 18 years or older
- The drug is prescribed by or in consultation with an oncologist or hematologist
- The beneficiary has documented biopsy or laboratory confirmed pemphigus vulgaris
- The beneficiary has a history of trial, failure, or intolerance with corticosteroids and either azathioprine, mycophenolate, or cyclophosphamide

Diffuse large B-cell lymphoma

- The drug is used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens for previously untreated diffuse large B-cell NHL; **OR**
- The drug is used in combination with chemotherapy (see above) for pediatric beneficiaries with previously untreated, advanced stage diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL); **OR**
- The drug is used in combination with Bendeka (bendamustine) and Polivy (polatuzumab vedotin-piiq).

COMPENDIA RECOMMENDED INDICATIONS

Thrombocytopenic purpura

- The beneficiary has previously failed or has a contraindication or intolerance to therapy with corticosteroids
- The beneficiary's diagnosis includes one of the following:
  - Primary thrombocytopenia
  - Idiopathic (Immune) thrombocytopenia purpura (ITP)
  - Evan's syndrome
  - Congenital and hereditary thrombocytopenic purpura
  - Thrombotic thrombocytopenic purpura in beneficiaries with ADAMTS13 deficiency

Chronic graft-versus-host disease (cGVHD)

- The beneficiary is post-allogeneic stem cell transplant (typically 3 or more months)
- The beneficiary has failed one or more previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids or immunosuppressants such as cyclosporine)
- The beneficiary has tried and had an inadequate response, contraindication, or intolerance to at least a three-month trial of ibrutinib

Autoimmune hemolytic anemia (AIHA)

- The beneficiary has warm-reactive disease refractory to or dependent on glucocorticoids
- The beneficiary has cold agglutinin disease with symptomatic anemia, transfusion-dependence, or disabling circulatory symptoms

Neuromyelitis optica spectrum disorder (NMOSD) – adult and pediatric

- The beneficiary has a confirmed diagnosis based on the following:
  - The beneficiary is seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
    - The beneficiary has at least one core clinical characteristic; **AND**
    - Alternative diagnoses have been excluded (e.g., sarcoidosis, cancer, chronic infection, etc.); **OR**
  - The beneficiary is seronegative for AQP-4 IgG antibodies OR has unknown AQP-4-IgG status; **AND**
    - The beneficiary has at least two core clinical characteristics occurring as a result of one or more clinical attacks
    - The beneficiary experienced ALL of the following:
      - At least 1 core clinical characteristic must be optic neuritis, acute myelitis with longitudinally extensive transverse myelitis (LETM), or area postrema syndrome
      - Dissemination in space (≥ 2 different core clinical characteristics)
      - Fulfillment of additional MRI requirements, as applicable
    - Alternative diagnoses have been excluded (e.g., sarcoidosis, cancer, chronic infection, etc.); **AND**
- The drug is used as a single agent or in combination with immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate, etc.)

Chronic inflammatory demyelinating polyneuropathy (CIDP)

- The beneficiary has refractory CIDP or CIDP associated with IgG4 antibodies to neurofascin or contactin.

Membranous nephropathy (MN)

- The drug is prescribed by or in consultation with a nephrologist.

Nodular lymphocyte-predominant B-cell Hodgkin lymphoma (NLPBL) (a.k.a. nodular lymphocyte predominant Hodgkin lymphoma [NLPHL])

- The drug is prescribed by or in consultation with an oncologist or hematologist.

Primary CNS lymphoma

- The drug is used in combination with high-dose methotrexate-based chemotherapy.

OFF-LABEL USES

- **Acute lymphoblastic leukemia**
  - The drug is used in combination with chemotherapy for CD-20 positive Philadelphia-chromosome negative B-cell acute lymphoblastic leukemia in adolescent and young adult beneficiaries and adults < 65 years of age without substantial comorbidities
- **Adult beneficiaries with dermatomyositis (DM)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating these conditions.
  - Limited to adults only, as use in juvenile dermatomyositis is considered investigational.
- **Systemic lupus erythematosus (SLE)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating these conditions.
- **Polymyositis (PM)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating these conditions.
- **Antibody-mediated rejection prevention in heart or kidney transplantation**
  - The drug is prescribed by or in consultation with a specialist familiar with treating these conditions.
- **Neurologic sarcoidosis (neurosarcoidosis)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease
- **Post-transplant lymphoproliferative disorder (PTLD)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
  - The drug can be approved as prophylaxis for PTLD at the time of Epstein-Barr virus (EBV) reactivation for beneficiaries at high risk of PTLD.
- **Adult and pediatric multiple sclerosis (MS)**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
- **Pediatric nephrotic syndrome (NS)**
  - The drug is prescribed by or in consultation with a nephrologist.
  - The drug is used for disease that is steroid-dependent (SDNS) or frequent-relapsing (FDNS).

- **Mucosa-associated lymphoid tissue (MALT) lymphoma**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
  - Rituximab may be used as alternative therapy for the early-stage disease at a radiation non-conducive site.
  - Late-stage (III and IV) disease may be treated either by rituximab alone or by a combination of rituximab and chemotherapy.
  - The drug may be used in combination therapy (e.g., rituximab plus bendamustine or rituximab plus CVP [chlorambucil, vincristine, prednisone]) for refractory disease following single-agent rituximab or for severely symptomatic beneficiaries with bulky disease.
- **Autoimmune hepatitis**
  - The beneficiary is intolerant or refractory to standard therapy.
- **Bullous pemphigoid**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
- **Anti–NMDA receptor (anti-NMDAR) encephalitis**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
- **Myelin oligodendrocyte glycoprotein (MOG)-associated disease (MOGAD).**
  - The beneficiary is diagnosed with relapsing disease.
    - **Note**: A first clinical event in MOGAD is not a currently established indication for long-term immunosuppression or immunomodulation.
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
- **HHV-8-negative/idiopathic multicentric Castleman disease**
  - The drug is prescribed by or in consultation with a specialist familiar with treating this disease.
  - The drug may be used with or without immunomodulators as second-line treatment for beneficiaries with mild/moderate disease who are not responding to IL6 blockade or who do not exhibit cytokine-driven symptomatology.
  - The drug may be used with or without corticosteroids as an alternative first-line treatment of IL6-targeted therapies.

EXCLUSIONS

Rituximab may NOT be approved for the following:

- Interstitial lung disease
- As first or second-line therapy for graft-versus-host disease

APPROVAL DURATION

Coverage will be provided for 6 months and may be renewed unless otherwise specified.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, tumor lysis syndrome [TLS], severe mucocutaneous reactions, progressive multifocal leukoencephalopathy [PML], viral hepatitis, serious bacterial, fungal, or viral infections, cardiac arrhythmias, renal toxicity, bowel obstruction or perforation)

- Documentation that the beneficiary has received clinical benefit from Rituxan therapy (e.g., disease symptoms have improved, disease has not progressed, disease is stabilized or with minimal change during treatment with rituximab)
- In beneficiaries with RA, documentation of use in combination with methotrexate

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9312 – Injection, rituximab, 10 mg; 1 billable unit = 10 mg
- J9311 – Injection, rituximab 10 mg and hyaluronidase: 1 billable unit = 10 mg
- Q5115 – Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
- Q5119 – Injection, rituximab-pvvr, biosimilar, (ruxience) 10 mg; 1 billable unit = 10 mg
- Q5123 – Injection, rituximab-arrx, biosimilar, (riabni), 10 mg; 1 billable unit = 10 mg

RUCONEST (C1 ESTERASE INHIBITOR)

Updated: 11/18/2025

INDICATIONS

Ruconest is indicated for treatment of:

- **Acute abdominal, peripheral, or facial attacks of hereditary angioedema (HAE)**

CLINICAL CRITERIA

- The drug must be prescribed by or in consultation with a residency-trained specialist in allergy, immunology, hematology, pulmonology, or medical genetics.
- The beneficiary must be at least 13 years of age.
- The beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or dosing based on support from official compendia.
- There is confirmation that the beneficiary is avoiding the following triggers for HAE attacks:
  - Helicobacter pylori infections (confirmed by lab tests)
  - Estrogen-containing oral contraceptive agents OR hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors
- The beneficiary has a history of:
  - Moderate to severe cutaneous or abdominal attacks; **OR**
  - Mild to severe airway swelling attacks of HAE (e.g., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)
- The beneficiary has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing (HAE with normal C1-INH [HAE Type III] will be reviewed on a case-by-case basis.):
  - HAE I (C1 inhibitor deficiency):
    - Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal, as defined by the laboratory performing the test)
    - Low C4 level (C4 below the lower limit of normal, as defined by the laboratory performing the test)
    - Low C1-INH functional level (C1-INH functional level below the lower limit of normal, as defined by the laboratory performing the test):
      - The beneficiary has a family history of HAE; **OR**
      - Normal C1q level
  - HAE II (C1-Inhibitor dysfunction):
    - Normal to elevated C1-INH antigenic level
    - Low C4 level (C4 below the lower limit of normal, as defined by the laboratory performing the test)
    - Low C1-INH functional level (C1-INH functional level below the lower limit of normal, as defined by the laboratory performing the test)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has significant and sustained improvement in severity and duration of attacks.
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, serious thrombotic events, laryngeal attacks, etc.)

DOSING

Acute hereditary angioedema (HAE) attack

- **The beneficiary's body weight is < 84 kg:**
  - 50 IU per kg body weight by intravenous injection
- **The beneficiary's body weight is ≥ 84 kg:**
  - 4200 IU (2 vials) by intravenous injection
- If attack symptoms persist, an additional (second) dose can be administered at the recommended dose level. Do not exceed 4200 IU per dose. No more than two doses should be administered within a 24-hour period.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0596 – Injection, C1 esterase inhibitor (recombinant), Ruconest, 10 units; 1 billable unit = 10 units

RYBREVANT (AMIVANTAMAB-VMJW)

Updated: 09/20/2024

INDICATIONS

Rybrevan is indicated for treatment of:

- **Non-small cell lung cancer (NSCLC)**

CLINICAL CRITERIA

- The drug is used in combination with carboplatin and pemetrexed for locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations in adult beneficiaries whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- The drug is used in combination with lazertinib (Lazcluze) for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations.
- The drug is used in combination with carboplatin and pemetrexed for the first-line treatment of adult beneficiaries with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations.
- The drug is used as a single agent for the treatment of locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations in adult beneficiaries whose disease has progressed on or after platinum-based chemotherapy.
- The drug is used as a single agent for subsequent therapy in beneficiaries who have not received prior amivantamab-vmjw therapy.
  - **Note**: In NCCN and UpToDate, for beneficiaries with EGFR exon 20 insertion mutation positive NSCLC who progressed on standard first-line therapy, the two choices for second-line therapy are Rybrevant (amivantamab) or Exkivity (mobocertinib).
  - Rybrevant (amivantamab) is a choice for the second-line treatment of NSCLC following progression on first-line chemotherapy in beneficiaries whose tumor harbors an exon 20 insertion mutation.
    - The only other alternative, docetaxel, has not been studied specifically in beneficiaries with this mutation and is best utilized following progression on amivantamab or mobocertinib.
- Rybrevant may be used as monotherapy for beneficiaries with metastatic/recurrent non-small cell lung cancer (NSCLC) who have had disease progression on prior platinum-based therapy, with or without prior immunotherapy (e.g., nivolumab, pembrolizumab, atezolizumab, durvalumab), and for whom the cancer is positive for an EGFR exon 20 mutation (confirmed by a standardized test)
  - **Note**: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for non-small cell lung cancer include Rybrevant (amivantamab-vmjw) as a subsequent therapy option with a Category 2A recommendation for beneficiaries who have progressed on or after platinum-based chemotherapy with or without immunotherapy and who have EGFR exon 20 insertion mutation-positive advanced NSCLC.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, interstitial lung disease, pneumonitis, dermatologic adverse reactions, such as acneiform dermatitis, and toxic epidermal necrolysis, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9061 – Injection, amivantamab-vmjw, 2 mg; 1 billable unit = 2 mg

RYSTIGGO (ROZANOLIXIZUMAB-NOLI)

Updated: 04/11/2024

INDICATIONS

Generalized Myasthenia Gravis (gMG)

- Rystiggo is indicated for the treatment of generalized myasthenia gravis (gMG) in adult beneficiaries who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has a documented diagnosis of generalized myasthenia gravis (gMG) and one of the following:
  - A positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **OR**
  - A positive serologic test for anti-muscle-specific tyrosine kinase (MuSK) antibodies.
- The beneficiary has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV.
- The beneficiary has documentation of baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 5.
- The prescribing physician is a neurologist or rheumatologist.
- Rystiggo is not being prescribed concurrently with other immunomodulatory biologic therapies (e.g., eculizumab [Soliris], ravulizumab [Ultomiris], efgartigimod alfa-fcab [Vyvgart], efgartigimod alfa and hyaluronidase-qvfc [Vyvgart Hytrulo]).

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that beneficiary has experienced a therapeutic response, as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9333 – Injection, efgartigimod alfa-fcab, 2 mg

RYTELO (IMETELSTAT)

Updated: 12/20/2024

INDICATIONS

Myelodysplastic syndrome (MDS)

- Rytelo is indicated for the treatment of low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks in adult beneficiaries who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESA).

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has International Prognostic Scoring System (IPSS) symptomatic low- to intermediate-1 risk disease.
- The beneficiary does not have del(5q) cytogenetic abnormality.
- The beneficiary is relapsed or refractory to erythropoiesis-stimulating agents (ESA) therapy or is ESA ineligible (i.e., EPO > 500 mU/mL).
- The beneficiary is red blood cell (RBC) transfusion dependent, defined as requiring at least 4 RBC units transferred over an 8-week period.
- The beneficiary has documentation of complete blood cell counts prior to initiation of Rytelo **AND** the provider agrees to obtain complete blood cell counts prior to each cycle thereafter for continued monitoring.

EXCLUSIONS

- Avoid use of drug in female beneficiaries of childbearing age due to potential for embryo-fetal toxicity, unless attestation or documentation is provided that the beneficiary is using effective contraception while taking Rytelo.
- Beneficiaries with del(5q) cytogenetic abnormality.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- **For first renewal**: Documentation that the beneficiary has achieved a reduction in RBC transfusion burden after at least 24 weeks (6 doses) from baseline.
- **For subsequent renewals**: Documentation that the beneficiary is experiencing disease response, as evidenced by a decrease in the number of RBC transfusions from baseline.

DOSAGE/ADMINISTRATION

Myelodysplastic syndromes (MDS)

- The recommended dosage of Rytelo is 7.1 mg/kg administered as an intravenous infusion over 2 hours every 4 weeks.
  - Discontinue Rytelo if the beneficiary does not experience a decrease in red blood cell (RBC) transfusion burden after 24 weeks of treatment (administration of 6 doses) or if unacceptable toxicity occurs at any time.
- Administer pre-treatment medications at least 30 minutes prior to dosing to prevent or reduce potential infusion-related reactions and monitor beneficiaries for adverse reactions for at least one hour after the infusion has been completed.
- Refer to prescribing information for recommended dosage modifications for adverse reactions.

Warnings and precautions

- **Thrombocytopenia**: If Grade 3 and Grade 4 thrombocytopenia occur, obtain complete blood cell counts prior to initiation of Rytelo weekly for the first two cycles and prior to each cycle thereafter to monitor. Delay or reduce dose as recommended.
- **Neutropenia**: If Grade 3 and Grade 4 neutropenia occur, obtain complete blood cell counts prior to initiation of Rytelo weekly for the first two cycles and prior to each cycle thereafter to monitor. Delay or reduce dose as recommended.
- **Infusion-related reactions**: Premedicate before infusion. Interrupt, decrease the rate of infusion, or permanently discontinue Rytelo, based on severity.
- **Embryo-fetal toxicity**: Can cause embryo-fetal harm. Advise females of reproductive potential of a potential risk to a fetus and to use effective contraception.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9999 – Not otherwise classified, antineoplastic drugs
- J0870 – Injection, imetelstat, 1 mg (effective January 1, 2025)

SANDOSTATIN LAR (OCTREOTIDE ACETATE)

Updated: 10/10/2024

INDICATIONS

Sandostatin is indicated for treatment of:

- **Acromegaly**
- **Severe diarrhea/flushing episodes** associated with metastatic carcinoid tumors
- **Profuse watery diarrhea** associated with vasoactive intestinal peptide (VIP)-secreting tumors

CLINICAL CRITERIA

Carcinoid tumors/neuroendocrine tumors (e.g., GI tract, lung, thymus, pancreas, adrenal)

- The beneficiary is 18 years of age or older.
- The drug is prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist.
- The drug is used to treat carcinoid tumors in beneficiaries with either carcinoid syndrome (severe diarrhea or flushing) or advanced disease, with or without carcinoid syndrome.
- The drug is used to treat symptoms related to hormone hypersecretion in pancreatic tumors.
- The drug is used in the primary treatment of unresected primary gastrinoma.
- The drug is used for the management of locoregional advanced or metastatic disease of the bronchopulmonary, thymic, or gastrointestinal tract.
- The drug is used for tumor control of unresectable or metastatic tumors of the pancreas.

Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) (pancreatic neuroendocrine [islet cell] tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma)

- The drug must be prescribed by or in consultation with a hematologist, oncologist, endocrinologist, or palliative care specialist.
- The drug is used to treat profuse watery diarrhea.

Acromegaly

- The beneficiary is an adult at least 18 years of age.
- The beneficiary's diagnosis is confirmed by elevated or equivocal serum IFG-1 as well as by inadequate suppression of growth hormone (GH) after a glucose load.
- The beneficiary has documented inadequate response to surgery or radiotherapy or it is not an option for the beneficiary.
- The drug is used is used as long-term maintenance therapy.
- The beneficiary's tumor has been visualized on imaging studies.
- Baseline growth hormone (GH) and IGF-1 blood levels are submitted at the time of the initial request (renewal will require reporting of current levels)

COMPENDIA APPROVED INDICATIONS

Thymic carcinomas/thymomas

- The drug is used with or without prednisone therapy

- The drug may be used as first line therapy or postoperative treatment in beneficiaries who are unable to tolerate first-line combination regimens
- The drug may be used as second line therapy for unresectable or metastatic disease

Neuroendocrine and adrenal tumors

- For treatment of neuroendocrine tumors (e.g., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI tract, lung, thymus, adrenal glands, and vasoactive intestinal polypeptidomas [VIPomas])

OFF-LABEL USES

For management of gastrointestinal hemorrhage, including hemorrhage caused by arteriovenous malformation, angioectasias, or angiodysplasias.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis, etc.)
  - Disease response with improvement in beneficiary's symptoms, including reduction in symptomatic episodes (e.g., diarrhea, rapid gastric dumping, flushing, bleeding, etc.), stabilization of glucose levels, or decrease in size of tumor or tumor spread
  - **Acromegaly ONLY**: Disease response indicated by reduction of growth hormone (GH) or IGF-I blood levels from baseline.
  - **Neuroendocrine tumors of the pancreas ONLY**: The beneficiary has had disease progression, and therapy will be continued in combination with systemic therapy in beneficiaries with functional tumors

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2353 – Injection, octreotide, depot form for intramuscular injection, 1 mg: 1 mg = 1 billable unit
- J2354 – Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg

SAPHNELO (ANIFROLUMAB-FNIA)

Updated: 02/04/2025

INDICATIONS

Saphnelo is indicated for treatment of:

- **Systemic lupus erythematosus (SLE)**

CLINICAL CRITERIA

- The beneficiary is ≥ 18 years of age.
- The beneficiary has a diagnosis of moderate to severe systemic lupus erythematosus
- Laboratory testing has documented the presence of autoantibodies (e.g., ANA, anti-dsDNA, anti-Sm, Anti-Ro/SSA, Anti-La/SSB).
- The beneficiary is currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic.
- The beneficiary is not receiving Saphnelo in combination with Benlysta (belimumab) or another biologic (e.g., Actemra, Benlysta, Cimzia, Enbrel, Humira, Kineret, Orencia, Remicade, Rituxan, Simponi, Stelara).
- The drug is prescribed by or in consultation with a rheumatologist.

OFF-LABEL USES

- **Discoid lupus erythematosus (DLE)**
  - Recommendations on photo protection, smoking cessation, and topical therapy remain the most evidence-based approaches for the majority of DLE beneficiaries.
  - Chronic DLE lesions that are not responsive to topical therapy or have a widespread disease involvement may be candidates for systemic therapy.
  - Below is a proposed therapeutic algorithm based on the strength of recommendations of the multiple treatment options

Proposed Treatment Algorithm for DLE	
Lifestyle measures (Mandatory)	• Photoprotection • Smoking cessation
First-line therapies	• Topical and intralesional corticosteroids • Topical calcineurin inhibitors
Second-line therapies	• Hydroxychloroquine • Chloroquine • **Note**: Hydroxychloroquine is preferred over chloroquine due to lower incidence of side effects or side effects are better tolerated.

Proposed Treatment Algorithm for DLE	
Third-line therapies	• Methotrexate • Systemic retinoids • Thalidomide, lenalidomide • Clofazimine • Azathioprine, mycophenolate mofetil, systemic corticosteroids, apremilast, IVIG
Fourth-line therapies	• Dapsone • Rituximab • Anti-IL-6 antibodies (e.g., tocilizumab, sarilumab) • Anti-JAK (tofacitinib, upadacitinib, etc.) • Type 1 interferon antagonists (anifrolumab-fnia [Saphnelo])

- **Juvenile dermatomyositis (JDM)**
  - Off-label use for juvenile disease
  - The beneficiary's disease must be recurrent or refractory to standard treatment (e.g., corticosteroids, methotrexate, hydroxychloroquine, IVIG, cyclosporine, mycophenolate mofetil).

DOSAGE AND ADMINISTRATION

The recommended dosage is 300 mg intravenous infusion over a 30-minute period every 4 weeks.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.).
- Documentation of positive clinical response, as evidenced by disease stability or improvement compared to pre-treatment baseline.
- The beneficiary is currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0491 – Injection, anifrolumab-fnia 1 mg; 1 billable unit = 1 mg.

SARCLISA (ISATUXIMAB-IRFC)

Updated: 09/22/2024

INDICATIONS

Sarclisa is indicated for treatment of:

- **Multiple myeloma**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The drug is prescribed by an oncologist or subspecialist who specializes in the treatment of multiple myeloma.
- The drug is used in combination with pomalidomide and dexamethasone to treat adults who have already received at least two therapies, including lenalidomide and a proteasome inhibitor.
- The drug is used in combination with carfilzomib (Kyprolis) and dexamethasone for the treatment of adult beneficiaries with relapsed or refractory multiple myeloma who have received 1 to 3 lines of therapy.
- The drug is used in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of newly diagnosed multiple myeloma in adult beneficiaries who are not eligible for autologous stem cell transplant.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, infections, second primary malignancies, hepatotoxicity, etc.)
- Absence of severe hypersensitivity to isatuximab-irfc or to any of its excipients

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9227 – Injection, isatuximab-irfc, 10 mg; 1 billable unit = 10 mg

SIGNIFOR LAR (PASIREOTIDE)

Updated: 10/23/2024

INDICATIONS

Signifor is indicated for treatment of:

- **Acromegaly**
- **Cushing's disease**

CLINICAL CRITERIA

Acromegaly

- The beneficiary has acromegaly and has had an inadequate response to surgery or surgery is not an option.
- The beneficiary has documentation of baseline growth hormone (GH) and IGF-1 blood levels.
- The drug is not used in combination with oral octreotide or with GH-analogues (e.g., pegvisomant)
- The drug must be prescribed by or in consultation with an endocrinologist.

Cushing's disease

- The beneficiary is 18 years or age or older.
- The drug must be prescribed by or in consultation with an endocrinologist.
- The beneficiary has either had surgery that was not curative OR is not a candidate for surgery.
- Baseline 24-hour urinary free cortisol (UFC) level, Adrenocorticotropic hormone (ACTH), or serum cortisol level has been obtained.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- **Acromegaly**
  - Disease response, as indicated by an improvement in signs and symptoms compared to baseline.
    - Reduction of growth hormone (GH) to < 1.0 mcg/L; **OR**
    - Age-adjusted normalization of serum IGF-1
- **Cushing's disease**
  - Disease response, as indicated by reduction in urinary free cortisol (UFC), plasma adrenocorticotropic hormone (ACTH), or serum cortisol levels from baseline

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2502 – Injection, pasireotide long acting, 1 mg; 1 billable unit = 1 mg

SIMPONI ARIA (GOLIMUMAB)

Updated: 11/16/2023

INDICATIONS

Simponi Aria is indicated for treatment of:

- **Moderately to severely active rheumatoid arthritis (RA)** in combination with methotrexate
- **Active psoriatic arthritis** in beneficiaries 2 years of age or older
- **Active ankylosing spondylitis**
- **Active polyarticular juvenile idiopathic arthritis (pJIA)** in beneficiaries 2 years of age or older

CLINICAL CRITERIA

- The beneficiary has been evaluated for tuberculosis and hepatitis B prior to initiating Simponi Aria
- The beneficiary does not have an active infection, including clinically important localized infections
- The drug must not be administered concurrently with live vaccines
- The beneficiary is not on concurrent treatment with another TNF inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast)

Rheumatoid arthritis

- The drug must be prescribed by or in consultation with a specialist in rheumatology
- The beneficiary has documented moderately to severely active disease
- The drug is prescribed in combination with methotrexate (unless contraindicated)

Psoriatic arthritis

- The drug must be prescribed by or in consultation with a specialist in dermatology or rheumatology
- The beneficiary has documented moderately to severely active disease
  - For beneficiaries with predominantly axial disease OR active enthesitis or dactylitis, the beneficiary has had a trial and failure of at least TWO non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; **OR**
  - For beneficiaries with peripheral arthritis, the beneficiary has had a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine)

Ankylosing spondylitis

- The drug must be prescribed by or in consultation with a specialist in rheumatology
- The beneficiary has documented active disease

Polyarticular juvenile idiopathic arthritis (pJIA)

- The drug must be prescribed by or in consultation with a specialist in dermatology or rheumatology
- The beneficiary has documented active disease

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., serious infections, cardiotoxicity or heart failure, malignancy, demyelinating disorders, lupus-like syndrome, severe hypersensitivity reactions, severe hematologic cytopenia, etc.)

Rheumatoid arthritis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as the number of tender and swollen joint counts or an improvement on a disease activity scoring tool (e.g., an improvement on a composite scoring index, such as Disease Activity Score-28 [DAS28] of 1.2 points or more or a ≥ 20% improvement on the American College of Rheumatology-20 [ACR20] criteria)

Psoriatic arthritis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as the number of tender and swollen joint counts or an improvement on a disease activity scoring tool (e.g., an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria [PsARC], 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria)

Ankylosing spondylitis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline, such as total back pain, physical function, morning stiffness, or an improvement on a disease activity scoring tool (e.g., an improvement of ≥ 1.1 on the Ankylosing Spondylitis Disease Activity Score [ASDAS] or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index [BASDAI])

Polyarticular juvenile idiopathic arthritis

- Disease response, as indicated by improvement in signs and symptoms compared to baseline.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1602 – Injection, golimumab, 1 mg, for intravenous use; 1 mg = 1 billable unit

SKYRIZI (RISANKIZUMAB-RZAA)

Updated: 07/24/2024

INDICATIONS

Skyrizi is indicated for treatment of adults with:

- **Moderate-to-severe plaque psoriasis**
- **Active psoriatic arthritis**
- **Moderate-to-severe Crohn's disease**
- **Moderate-to-severe ulcerative colitis**

CLINICAL CRITERIA

- For all indications, the beneficiary should be evaluated for tuberculosis (TB) prior to initiating treatment with Skyrizi.

Moderate-to severe plaque psoriasis

- The beneficiary is at least 18 years of age
- The beneficiary has had an inadequate treatment response, intolerance, or contraindication to a trial of at least one biologic DMARD (e.g., Humira [adalimumab], Orencia [abatacept], Enbrel [etanercept], Simponi Aria [golimumab], Remicade [infliximab], Inflectra [infliximab-dyyb], Rituxan [rituximab], etc.)

Active psoriatic arthritis

- The beneficiary is at least 18 years of age
- The beneficiary has had an inadequate treatment response, intolerance, or contraindication to a trial of at least one biologic DMARD (e.g., Humira [adalimumab], Orencia [abatacept], Enbrel [etanercept], Simponi Aria [golimumab], Remicade [infliximab], Inflectra [infliximab-dyyb], Rituxan [rituximab], etc.)

Moderate-to-severe Crohn's disease

- The beneficiary is at least 18 years of age
- The beneficiary has had an inadequate treatment response, intolerance, or contraindication to a trial of a non-biologic or biologic DMARD (e.g., Imuran [azathioprine], Humira [adalimumab], Cimzia [certolizumab], Remicade [infliximab], Inflectra [infliximab-dyyb], etc.)

Moderate-to-severe ulcerative colitis

- The beneficiary is at least 18 years of age
- The beneficiary has had an inadequate treatment response, intolerance, or contraindication to a trial of a non-biologic or biologic DMARD (e.g., Imuran [azathioprine], Humira [adalimumab], Cimzia [certolizumab], Remicade [infliximab], Inflectra [infliximab-dyyb], etc.)

DOSAGE AND ADMINISTRATION

Plaque psoriasis and psoriatic arthritis

- The prescriber will not exceed the FDA labeled maintenance dose of 150 mg every 12 weeks.

- In beneficiaries with psoriatic arthritis, Skyrizi can be administered alone or in combination with **non-biologic** disease-modifying antirheumatic drugs (DMARDs)

Crohn's disease

- The beneficiary's liver enzymes and bilirubin levels will be obtained prior to initiating treatment.
- The prescriber will not exceed the FDA labeled maintenance dose of 360 mg every 8 weeks.

Ulcerative colitis

- The beneficiary's liver enzymes and bilirubin levels will be obtained prior to initiating treatment.
- The prescriber will not exceed the FDA labeled maintenance dose of 360 mg every 8 weeks.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary's condition has improved or stabilized with Skyrizi
- The drug is not used in combination with any other biologic DMARD (e.g., Imuran [azathioprine], Humira [adalimumab], Cimzia [certolizumab], Remicade [infliximab], Inflectra [infliximab-dyyb], etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2327, injection, risankizumab-rzaa, intravenous, 1 mg

SOLIRIS (ECULIZUMAB)

Updated: 08/05/2025

INDICATIONS

Soliris is indicated for the following:

- **Paroxysmal nocturnal hemoglobinuria (PNH)** to reduce hemolysis
- **Atypical hemolytic uremic syndrome (aHUS)** to inhibit complement-mediated thrombotic microangiopathy
- **Generalized myasthenia gravis (gMG)** in beneficiaries who are anti-acetylcholine receptor (AchR) antibody positive
- **Neuromyelitis optica spectrum disorder (NMOSD)** in adult beneficiaries who are anti-aquaporin-4 (AQP4) antibody positive

CLINICAL CRITERIA

- The beneficiary does not have a systemic infection.

Paroxysmal nocturnal hemoglobinuria (PNH)

- The drug must be prescribed by or in consultation with a hematologist
- The beneficiary is 18 years of age or older
- The beneficiary has one of the following indications for therapy:
  - Presence of a thrombotic event
  - Presence of organ damage secondary to chronic hemolysis
  - The beneficiary is pregnant and potential benefit outweighs potential fetal risk
  - The beneficiary is transfusion dependent
  - The beneficiary has high LDH activity (defined as ≥ 1.5 x upper limits of normal) with clinical symptoms
- The beneficiary has documented baseline values for one or more of the following (necessary for renewal):
  - Serum lactate dehydrogenase (LDH)
  - Hemoglobin level
  - Packed RBC transfusion requirement

Atypical hemolytic uremic syndrome (aHUS)

- The drug must be prescribed by or in consultation with a hematologist or nephrologist
- The beneficiary is 2 months of age and older
- A diagnosis of thrombocytopenic purpura (TTP) has been excluded by ADAMTS 13 activity ≥ 20%.
- Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out
- The beneficiary has documented baseline values for one or more of the following (necessary for renewal):
  - Serum lactate dehydrogenase (LDH)
  - Serum creatinine/eGFR

- Platelet count
- Plasma exchange/infusion requirement

Generalized myasthenia gravis (gMG)

- The adult or pediatric beneficiary is 6 years of age or older.
- The prescribing physician is a neurologist.
- The beneficiary has a documented diagnosis of generalized Myasthenia Gravis.
- The beneficiary has documentation of a positive serologic test for anti-acetylcholine antibodies.
- The beneficiary has documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis.
- The beneficiary has documentation of baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 5.
- The beneficiary has documentation that they have tried and failed or have a contraindication to 2 or more conventional therapies (e.g., acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies).

Neuromyelitis optica spectrum disorder (NMOSD)

- The drug must be prescribed by or in consultation with a neurologist
- The beneficiary has documented anti-aquaporin-4 (AQP4) antibody positive disease
- The beneficiary has a history of at least 2 relapses in the past 12 months; **OR**
  - The beneficiary has a history of at least 3 relapses in the past 24 months with at least 1 relapse in the previous 12 months
- The beneficiary had an inadequate response or contraindication to corticosteroids
- The beneficiary had an inadequate response or contraindication to rituximab (Rituxan)
- The beneficiary had an inadequate response to a trial (e.g., 3 months) of **ONE** or more of the following:
  - Azathioprine
  - Mycophenolate mofetil
  - Methotrexate
- There is no evidence of an active meningococcal infection

EXCLUSIONS

- Soliris is not indicated for treatment of beneficiaries with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- Soliris is not being prescribed or used in combination with other immunomodulatory biologic therapies (e.g., rituximab [Rituxan], efgartigimod alfa-fcab [Vyvgart], satralizumab [Enspryng], inebilizumab [Uplizna], ravulizumab-cwvz [Ultomiris], etc.)

OFF-LABEL USE

Systemic lupus erythematosus (SLE)

- Beneficiary has a diagnosis of systemic lupus erythematosus (SLE) associated with thrombotic microangiopathy or co-existent lupus nephritis.

APPROVAL DURATION

- **PNH and aHUS**: Authorization will be provided for 6 months and may be renewed for an additional 6 months; however, reauthorization will be for no more than 12 months.
- **gMG**: Initial authorization will be for 6 months and may be renewed; however, reauthorization will be for no more than 12 months.
- **NMOSD**: Authorization will be provided for 6 months and may be renewed for an additional 6 months; however, reauthorization will be for no more than 12 months.
- **SLE**: Authorization will be provided for 6 months and may be renewed for an additional 6 months; however, reauthorization will be for no more than 12 months.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., infusion reactions, serious infections, etc.)
- Disease response, as indicated by one or more of the following:
  - **PNH**
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in hemoglobin level from pretreatment baseline
    - Decrease in packed RBC transfusion requirement from pretreatment baseline
  - **aHUS**
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline
    - Increase in platelet count from pretreatment baseline
    - Decrease in plasma exchange/infusion requirement from pretreatment baseline
  - **gMG**
    - Documentation that the beneficiary has experienced a therapeutic response, as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline
  - **NMOSD**
    - The beneficiary has a beneficial response from drug therapy, including either the absence of relapse or reduction in relapses (documentation must be provided).
    - For continuation of therapy, the beneficiary will not be receiving rituximab (Rituxan) concurrently, and the beneficiary's diagnosis has been confirmed as anti-aquaporin-4 (AQP4) antibody positive disease.
  - **SLE**
    - The beneficiary has a beneficial response from drug therapy, including either the absence of relapse or reduction in relapses (documentation must be provided).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1300 – Injection, eculizumab, 10 mg; 1 billable unit = 10 mg

ICD-10 Diagnosis Codes

- D59.3 Hemolytic-uremic syndrome
- D59.5 Paroxysmal nocturnal hemoglobinuria (Marchiafava-Micheli)
- G70.00 Myasthenia gravis without (acute) exacerbation
- G36.0 Neuromyelitis optica (Devic)

SPEVIGO (SPESOLIMAB-SBZO)

Updated: 06/13/2024

INDICATIONS

Spevigo is indicated for the treatment of **generalized pustular psoriasis (GPP)** in adults and pediatric beneficiaries 12 years of age or older and weighing at least 40 kg.

CLINICAL CRITERIA

Generalized pustular psoriasis (GPP)

- The medication is prescribed by or in consultation with a dermatologist.
- The beneficiary has a diagnosis of generalized pustular psoriasis (GPP) and is experiencing an acute, moderate-to-severe intensity disease flare based on one of the following:
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate); **OR**
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score ≥ 2 (mild); **OR**
  - Erythema and pustules cover ≥ 5% of body-surface area; **OR**
  - New appearance or worsening of pustules
- The beneficiary will not use the drug concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate, etc.) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus, etc.) for the same indication.

APPROVAL DURATION

Approval is for two doses (900 mg each)

DOSAGE AND ADMINISTRATION

Subcutaneous dosage for treatment of GPP when not experiencing a flare:

- Administer a subcutaneous loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later and every 4 weeks thereafter.

Subcutaneous use after intravenous SPEVIGO for treatment of GPP flare:

- Four weeks after treatment with intravenous Spevigo, initiate or reinitiate subcutaneous Spevigo at a dose of 300 mg (two 150 mg injections) administered every 4 weeks. A loading dose is not required following treatment of a GPP flare with intravenous Spevigo.

Intravenous dosage for treatment of GPP flare

- Administer as a single 900 mg dose by intravenous infusion over 90 minutes. If flare symptoms persist, an additional intravenous 900 mg dose may be administered one week after the initial dose.

RENEWAL/REAUTHORIZATION

May not be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1747 – Injection, spesolimab-sbzo, 1 mg

SPINRAZA (NUSINERSEN)

Updated: 05/01/2024

INDICATIONS

Spinraza is indicated for the treatment of **spinal muscular atrophy** in pediatric and adult beneficiaries.

CLINICAL CRITERIA

- The beneficiary has a documented diagnosis of spinal muscular atrophy type 1, 2, or 3 that is confirmed either by homozygous deletion of the SMN1 gene or by dysfunctional mutation of the SMN1 gene.
- The drug is prescribed by or in consultation with a neurologist with special qualifications in child neurology and treatment of spinal muscular atrophy.
- The beneficiary has documentation of baseline (pre-treatment) motor function skills
- The beneficiary is not using Spinraza concomitantly with Evrysdi (risdiplam).
- The beneficiary has not previously received gene replacement therapy for the treatment of SMA

EXCLUSIONS

- Severe contracture (any contracture that could interfere with assessment of motor function skills test)
- The beneficiary has evidence of severe scoliosis on radiography (spine curvature with a Cobb angle of > 40 degrees)
- The beneficiary is ventilator dependent.

APPROVAL DURATION

Coverage will be provided for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity that would preclude safe administration of the drug (e.g., significant renal toxicity, thrombocytopenia, coagulation abnormalities, etc.)
- The beneficiary has responded to therapy compared to pre-treatment baseline in one or more of the following:
  - Stability or improvement in net motor function/milestones score
  - Stability or improvement in respiratory function
  - Reduction in exacerbations necessitating hospitalization or antibiotic therapy for respiratory infection in the preceding year or timeframe
- In the absence of beneficiary improvement after drug therapy, a review of benefit, necessity, and value of Spinraza is required.

BILLING/CODING INFORMATION

Applicable Service Codes

- J3490 – Unclassified drugs

- J3590 – Unclassified biologics
- C9489 – Injection, nusinersen, 0.1 mg (effective 7/1/17)
- J2326 – Injection, nusinersen, 0.1 mg (effective 1/1/18)

SPRAVATO (ESKETAMINE)

Updated: 12/30/2024

INDICATIONS

Spravato is indicated in conjunction with an oral antidepressant for the treatment of:

- **Treatment-resistant depression (TRD)**
- **Depressive symptoms in adults with major depressive disorder (MDD)** with acute suicidal ideation or behavior

CLINICAL CRITERIA

- The beneficiary must have a diagnosis of treatment-resistant depression (TRD)
  - The beneficiary meets the DSM-5 diagnostic criteria for:
    - Major depressive disorder (MDD); **OR**
    - Recurrent MDD without psychotic features
- The beneficiary must be 18 years of age or older.
- The beneficiary has tried and failed treatment with a minimum of THREE separate therapeutic trials, including antidepressants from at least TWO different drug classes (SSRI, SNRI and bupropion), as well as at least ONE trial of augmentation therapy with one of the following:
  - Atypical antipsychotic
  - Lithium
  - Antidepressant from a different class
- The beneficiary must be taking Spravato (esketamine) in conjunction with an oral antidepressant.
- The beneficiary's treatment protocol will be reviewed for compliance on previous therapies with at least EIGHT weeks EACH for the nonconcurrent monotherapies at maximally tolerated doses
- The beneficiary should not be approved for or continue on this therapy with any of the following:
  - The beneficiary is pregnant or breastfeeding
  - The beneficiary has active moderate to severe substance or alcohol use disorder
  - The beneficiary has aneurysmal vascular disease
  - History of intracerebral hemorrhage
  - Hypersensitivity to esketamine, ketamine, or any of the components of the medication
- The prescriber must submit ALL of the following:
  - Current chart notes
  - Documentation of previous failed therapies
  - Documentation of trial and response, if the beneficiary tried IV ketamine
  - Baseline depression assessment using a validated depression rating scale
  - A treatment plan for possible serious cardiac adverse event during treatment session (i.e., access to emergency care)
- Other uses of Spravato are considered **investigational** and therefore are not approved.

APPROVAL DURATION

- Initial approval is for 1 month (4 weeks) only.

- Maintenance approval is for 6 months.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has shown a positive clinical response to therapy, defined by at least a 50% reduction of total MADRS score from baseline.
- Absence of any unacceptable toxicity (e.g., dissociation, cognitive impairment, suicidal thoughts, etc.)
- Absence of signs/symptoms of abuse or misuse

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0013 – Esketamine, nasal spray, 1 mg; 1 billable unit = 1 mg

STELARA (USTEKINUMAB)

Updated: 01/23/2024

INDICATIONS

Stelara is indicated for treatment of:

- Adult beneficiaries with:
  - **Moderate to severe plaque psoriasis** in beneficiaries who are candidates for phototherapy or systemic therapy
  - **Active psoriatic arthritis**, alone or in combination with methotrexate.
  - **Moderate to severely active Crohn's disease**
  - **Moderate to severely active ulcerative colitis**
- Pediatric beneficiaries 6 years of age or older with:
  - **Moderate to severe plaque psoriasis** in beneficiaries who are candidates for phototherapy or systemic therapy
  - **Active psoriatic arthritis**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older (unless otherwise specified)
- The beneficiary has had baseline disease severity assessed utilizing an objective measure/tool.
- The beneficiary is not on concurrent treatment with a TNF-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, upadacitinib, etc.)

Plaque psoriasis

- The beneficiary is 6 years of age or older (FDA indicated age)
- The beneficiary has had moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles, genitalia)
- The beneficiary did not respond adequately to or is not a candidate for a trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressive agents, keratolytic agents, retinoic acid derivatives, or vitamin D analogues); **OR**
- The beneficiary did not respond adequately to or is not a candidate for a trial of phototherapy (e.g., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

Adult psoriatic arthritis

- The beneficiary has a documented diagnosis of moderate to severely active disease.
  - For beneficiaries with predominantly axial disease OR active enthesitis or dactylitis, the beneficiary had a trial and failure of at least ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**

- For beneficiaries with peripheral arthritis, the beneficiary had a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD), such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine

Juvenile psoriatic arthritis

- The beneficiary is 6 years of age or older (FDA indicated age).
- The beneficiary has a documented diagnosis of moderate to severely active disease.
- The drug may be used as a single agent or in combination with methotrexate.
- The beneficiary has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

Crohn's disease

- The beneficiary has a documented diagnosis of moderate to severely active disease.

Ulcerative colitis

- The beneficiary has a documented diagnosis of moderate to severely active disease.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., serious infections, malignancy, severe hypersensitivity reactions, reversible posterior leukoencephalopathy syndrome, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- **J-code:**
  - J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg
  - J3358 – Ustekinumab, for intravenous injections, 1 mg; 1 billable unit = 1 mg
- **NDC:**
  - Stelara 45 mg vial and prefilled syringe: 57894-0060-xx
  - Stelara 90 mg prefilled syringe: 57894-0061-xx
  - Stelara 130 mg (5 mg/mL) single-dose vial: 57894-0054-xx

STRENSIQ (ASFOTASE ALFA)

Updated: 12/30/2024

INDICATIONS

Strensiq is indicated for treatment of:

- **Perinatal/infantile-onset hypophosphatasia (HPP)**
- **Juvenile onset hypophosphatasia (HPP)**

CLINICAL CRITERIA

- The prescriber is a specialist in the area of the beneficiary's disease (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the beneficiary's disease.
- The beneficiary is ≤ 18 years of age at onset
- The beneficiary has baseline serum alkaline phosphatase (ALP) activity below the age and gender-adjusted normal range
- The beneficiary has a diagnosis of HPP confirmed by the presence of elevated ALP substrate levels (increased serum pyrodoxal 5'-phosphate [PLP] or urinary phosphoethanolamine [PEA])
- The beneficiary has at least one pathogenic variant in ALPL gene
- The beneficiary has documentation of at least ONE of the following prior to the age of 18:
  - Symptoms:
    - Vitamin B6-dependent seizures
    - Respiratory insufficiency
    - Hypotonia
    - Loss of deciduous teeth before the age of four
    - Low trauma or non-traumatic fractures, with supporting historical documentation and radiographic evidence of the fracture
    - Gait disturbance, such as delayed walking or waddling gait (e.g., 6-minute walk test showing lower than expected results)
    - Osteopenia, osteoporosis, or low bone mineral content for age attributable to hypophosphatasia
  - Radiologic evidence
    - Genu Valgum (knock knees)
    - Rachitic chest
    - Bowing of legs
    - Craniosynostosis
    - Infantile rickets
    - Osteochondral spurs

APPROVAL DURATION

- Initial authorization is for 6 months
- Reauthorization is for 12 months (1 year)

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Strensiq carries a Black Box Warning from the FDA for hypersensitivity reactions including anaphylaxis. If a severe hypersensitivity reaction occurs, discontinue Strensiq and initiate medical treatment.
- Laboratory documentation must be provided confirming a decrease in level of alkaline phosphatase (ALP) substrate
- Provider should have documentation of annual renal ultrasound and retinal exam for calcium deposition
- Documentation of one or more of the following that were originally utilized to support initial medical necessity for the medication:
  - Radiographic evidence of improvement in skeletal deformities or growth
  - Improvement in 6-minute walk test (if applicable)
  - Improvement in bone density
  - Reduction in fractures

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3490 – Unclassified drugs

SUPPRELIN LA (HISTRELIN ACETATE)

Updated: 12/30/2024

INDICATIONS

Supprelin LA is indicated for treatment of:

- **Children with central precocious puberty (CPP)**

CLINICAL CRITERIA

- The drug is prescribed by or in consultation with a pediatric endocrinologist.
- The beneficiary has a diagnosis of central precocious puberty
- The beneficiary had an early onset of secondary sexual characteristics:
  - Male: earlier than 9 years of age
  - Female: earlier than 8 years of age
- The beneficiary has advanced bone age of at least one year compared to chronological age
  - The beneficiary has undergone gonadotropin-releasing hormone agonist (GnRH) testing
  - The beneficiary has a peak luteinizing hormone (LH) level above pre-pubertal range **OR** the beneficiary has a random LH level in the pubertal range
- The beneficiary had the following diagnostic evaluations to rule out tumor, when suspected:
  - Diagnostic imaging of the brain (MRI or CT scan)
  - Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)
  - Human chorionic gonadotropin levels (in all male beneficiaries)
  - Adrenal steroids to rule out congenital adrenal hyperplasia

APPROVAL DURATION

Supprelin LA is subject to a quantity limit of one subcutaneous implant every 12 months

RENEWAL/REAUTHORIZATION

Continued use of Supprelin LA will be reviewed at least every 12 months to confirm the following:

- Consideration for discontinuation of therapy at 11 years of age for females and 12 years of age for males
- LH levels have been suppressed to pre-pubertal levels

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9226 – Histrelin implant (Supprelin LA), 50 mg: 1 billable unit = 50 mg

SUSTOL (GRANISETRON EXTENDED RELEASE)

Updated: 12/30/2024

INDICATIONS

Sustol (granisetron) is indicated for:

- Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

CLINICAL CRITERIA

Prevention of chemotherapy-induced nausea and vomiting

- The beneficiary is 2 years of age or older.
- The drug is administered in combination with dexamethasone.
- The beneficiary is receiving highly emetogenic chemotherapy (HEC) (see table below); **AND**
  - The beneficiary has failed with palonosetron while receiving the current chemotherapy regimen.
- The beneficiary is receiving a regimen that is not considered to be HEC; **AND**
  - The beneficiary has failed with BOTH of the following while receiving the current chemotherapy regimen (failure is defined as two or more documented episodes of vomiting attributed to the current chemotherapy regimen):
    - Ondansetron (Zofran) or granisetron (Kytril); **AND**
    - Palonosetron

Highly / Moderately Emetogenic Chemotherapy (HEC/MEC)	
Highly Emetogenic Chemotherapy (HEC)	**Moderately Emetogenic Chemotherapy (MEC)**
Carboplatin	Aldesleukin
Carmustine	Amifostine
Cisplatin	Arsenic Trioxide
Cyclophosphamide	Azacitidine
Dacarbazine	Bendamustine
Doxorubicin	Busulfan
Epirubicin	Clofarabine
Ifosfamide	Cytarabine
Mechlorethamine	Dactinomycin
Streptozocin	Daunorubicin
	Dinutuximab
	Idarubicin
	Interferon alfa
	Irinotecan
	Melphalan
	Methotrexate
	Oxaliplatin

Highly / Moderately Emetogenic Chemotherapy (HEC/MEC)	
	Temozolomide
	Trabectedin
The following regimens can be considered HEC	
FOLFOX	

EXCLUSIONS

- Breakthrough emesis
- Repeat dosing in multi-day emetogenic chemotherapy regimens

APPROVAL DURATION

Authorization is for six months

RENEWAL/REAUTHORIZATION

May NOT be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1627 – Injection, granisetron, extended-release, 0.1 mg; 1 billable unit = 0.1 mg

SYFOVRE (PEGCETACOPLAN)

Updated: 08/07/2025

INDICATIONS

Syfovre is indicated for the treatment of:

- **Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of geographic atrophy (GA), as defined by a phenotype of central geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) or choriocapillaris atrophy.
- The beneficiary's disease is secondary to age-related macular degeneration.
- The beneficiary has a baseline assessment for best corrected visual acuity (BCVA) and a quantitative description of lesion size (e.g., loss of retinal pigmented epithelium [RPE]) as determined by Fundus Auto Fluorescence (FAF) (usually specified in terms of optic disc area [DA] or disc diameters [DD], e.g., "FAF: RPE Loss 2 DA").
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.)
- The beneficiary is ≥ 50 years of age.
- Syfovre is prescribed by an ophthalmologist.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., endophthalmitis, retinal detachment, retinal vasculitis or retinal vascular occlusion, neovascular [wet] AMD or choroidal neovascularization, intraocular inflammation [e.g., vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare], increased intraocular pressure, etc.)
- The beneficiary has had disease stabilization or slowing of the rate of disease progression while on Syfovre compared to pre-treatment baseline, as measured by best corrected visual acuity (BCVA) with every request and Fundal Autofluorescence (FAF) at least annually.

RECOMMENDED DOSING

Recommended dose for Syfovre is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2781 – Injection, pegcetacoplan, intravitreal, 1 mg; 1 billable unit = 1 mg

SYLVANT (SILTUXIMAB)

Updated: 01/16/2024

INDICATIONS

Sylvant is indicated for treatment of:

- **Multicentric Castleman's disease (MCD) in beneficiaries who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.**

Limitations of use: Sylvant was not studied in beneficiaries with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

CLINICAL CRITERIA

Multicentric Castleman's disease (MCD)

- The beneficiary has a diagnosis of multicentric Castleman's disease.
- The beneficiary is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary is 18 years of age or older.
- The beneficiary has documentation of C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR)
- The drug is prescribed as a single agent for multicentric Castleman's disease (MCD)

COMPENDIA RECOMMENDED INDICATIONS

Relapsed/refractory unicentric Castleman's disease (UCD)

- The beneficiary has a diagnosis of relapsed/refractory Castleman's disease.
- The beneficiary is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary is 18 years of age or older.
- The beneficiary has documentation of C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR)
- The drug is prescribed as single-agent therapy for Unicentric Castleman's disease (UCD):
  - For UCD, drug is used as second-line therapy for relapsed or refractory disease.

Cytokine release syndrome

- Sylvant (siltuximab) may be prescribed for the treatment of chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome when either of the following criteria are met:
  - Cytokine release syndrome is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); **OR**
  - The requested medication will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

APPROVAL DURATION

Approval is for 6 months.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding to therapy, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug, (e.g., gastrointestinal perforation, severe infusion related reactions and hypersensitivity, etc.)

BILLING/CODING INFORMATION

- J2860 – Injection, siltuximab, 10 mg; 10 mg = 1 billable unit

TALVEY (TALQUETAMAB-TGVS)

Updated: 12/19/2024

INDICATIONS

Multiple myeloma

- Talvey is indicated for the treatment of relapsed or refractory multiple myeloma in adult beneficiaries who have received at least four lines of therapy.

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has a diagnosis of relapsed or refractory multiple myeloma.
- The beneficiary has received at least four prior lines of therapy, including all of the following:
  - An immunomodulatory agent (e.g., lenalidomide, thalidomide); **AND**
  - A protease inhibitor (e.g., bortezomib, carfilzomib); **AND**
  - A CD38-directed monoclonal antibody (e.g., daratumumab)
- The drug is prescribed by or in consultation with an oncologist.
- The prescriber is enrolled in the TECVAYLI-TALVEY REMS program.
- Talvey is used as continuation therapy following administration of all step-up doses.
- Talvey should only be administered by a qualified healthcare professional with appropriate medical support in order to manage severe reactions, such as CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

APPROVAL DURATION

After the initial hospital administration of three step-up titration doses, approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has documentation of disease response with treatment and no evidence of progressive disease while on therapy.
- Absence of unacceptable toxicity from Talvey (e.g., severe oral toxicity and weight loss, serious life-threatening infections, severe cytopenia, severe dermatologic toxicity, hepatotoxicity, neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome [ICANS], cytokine release syndrome [CRS], etc.)

DOSING

- **Weekly Dosing Schedule:**
  - Step-up Dose:
    - 0.01 mg/kg on day 1
    - 0.06 mg/kg on day 4
  - Treatment dose:

        - 0.4 mg/kg on day 7
        - 0.4 mg/kg once weekly until disease progression or unacceptable toxicity
- **Biweekly Dosing Schedule:**
    - Step-up dose:
        - 0.01 mg/kg on day 1
        - 0.06 mg/kg on day 4
        - 0.4 mg/kg on day 7
    - Treatment dose:
        - 0.8 mg/kg on day 10
        - 0.8 mg/kg every 2 weeks until disease progression or unacceptable toxicity

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3055 – Injection, talquetamab-tgvs, 0.25 mg

TECARTUS (BREXUCABTAGENE AUTOLEUCEL)

Updated: 08/22/2025

INDICATIONS

Tecartus is indicated for treatment of:

- **Relapsed or refractory mantle cell lymphoma (r/r MCL)**
- **Adult beneficiaries with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukemia (ALL)**

CLINICAL CRITERIA

Mantle cell lymphoma

- The beneficiary is an adult with pathology-confirmed relapsed or refractory mantle cell lymphoma
- The beneficiary has at least one measurable lesion
- The beneficiary does not have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells, or brain metastases
- The beneficiary has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis)
- The beneficiary has received ≥ 1 and ≤ 5 prior MCL-targeted lines of treatment, which must have included:
  - A chemotherapy regimen containing an anthracycline or bendamustine
  - An anti-CD20 monoclonal antibody therapy (e.g., rituximab)
  - A Bruton's tyrosine kinase (BTK) inhibitor (ibrutinib [Imbruvica] or acalabrutinib [Calquence])

B-cell precursor acute lymphoblastic leukemia (ALL)

- The beneficiary has relapsed or refractory disease
- The beneficiary has morphological disease in the bone marrow (≥ 5% blasts)
- The beneficiary has not received prior anti-CD19 therapy other than blinatumomab. In beneficiaries previously treated with blinatumomab, testing must show cluster of differentiation 19 (CD19) tumor expression in bone marrow or peripheral blood.
- The beneficiary does not have CNS2 disease (< 5 WBC in the CSF with blasts) or CNS3 disease (≥ 5 WBC in the CSF with blasts); **AND**
  - The beneficiary has Philadelphia chromosome (Ph)-positive disease; **AND**
    - The beneficiary's disease is tyrosine kinase inhibitor (TKI)-intolerant or is refractory to at least two different TKIs; **OR**
  - The beneficiary has Philadelphia chromosome (Ph)-negative disease

EXCLUSIONS

- Prior allogeneic HSCT (alloHSCT)
- Prior genetically modified T-cell therapy, including CAR T-cells
- History of human immunodeficiency virus (HIV) infection
- Active or uncleared hepatitis B virus (HBV) or hepatitis C virus (HCV) infection

- Clinically significant cardiac disease, including active arrhythmias, within the prior 12 months

APPROVAL DURATION

Approval is for one treatment course (1 dose of Tecartus) and may not be renewed

RENEWAL/REAUTHORIZATION

May NOT be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Q2053 – Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t-cells, including leukapheresis and dose preparation procedures, per therapeutic dose; 1 billable unit = 200 million autologous anti-cd19 car positive viable t-cells.

TECENTRIQ (ATEZOLIZUMAB), TECENTRIQ HYBREZA (ATEZOLIZUMAB AND HYALURONIDASE-TQJS)

Updated: 10/07/2025

INDICATIONS

Tecentriq and Tecentriq Hybreza are indicated for:

- **Non-small cell lung cancer (NSCLC)**
- **Small cell lung cancer**
- **Hepatocellular carcinoma (HCC)**
- **Melanoma**
- **Alveolar soft part sarcoma (ASPS) (*see pediatric indication below)**

CLINICAL CRITERIA

- The beneficiary must be at least 18 years of age, unless otherwise indicated.
- The beneficiary has not experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (except when used in combination with ipilimumab as second-line or subsequent therapy for metastatic or unresectable melanoma following progression on single agent anti-PD-1 immunotherapy).

Non-small cell lung cancer (NSCLC)

- The drug is used as adjuvant treatment following resection and platinum-based chemotherapy in beneficiaries with stage II to IIIA NSCLC whose tumors have high PD-L1 expressions on ≥ 1% or tumor cells.
- The drug is used for the first-line treatment of metastatic NSCLC in adult beneficiaries whose tumors have high PD-L1 expression or PD-L1 stained tumor-infiltrating tumor cells covering ≥ 10% of the tumor area, with no EGFR or ALK genomic tumor aberrations.
- The drug is used in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of metastatic non-squamous NSCLC in adult beneficiaries with no EGFR or ALK genomic tumor aberrations.
- The drug is used in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of metastatic non-squamous NSCLC in adult beneficiaries with no EGFR or ALK genomic tumor aberrations.
- The drug is used for the treatment of metastatic NSCLC in adult beneficiaries who have disease progression during or following platinum-containing chemotherapy. Beneficiaries with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq or Tecentriq Hybreza.

Small-cell lung cancer (SCLC)

- The drug is used in combination with carboplatin and etoposide for the first-line treatment of extensive-stage small cell lung cancer in adult beneficiaries.
- The drug is used in combination with lurbinectedin (Zepzelca) for maintenance treatment of ES-SCLC in adult beneficiaries whose disease has not progressed after first-line induction therapy with the following:

- Tecentriq Hybreza or intravenous atezolizumab (Tecentriq); **AND**
- Carboplatin plus etoposide.

Hepatocellular carcinoma (HCC)

- The drug is used in combination with bevacizumab for the treatment of unresectable or metastatic HCC in beneficiaries who have not received prior systemic therapy.

Melanoma

- The drug is used in combination with cobimetinib and vemurafenib for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma in beneficiaries.

Alveolar soft part sarcoma (ASPS)

- Tecentriq (atezolizumab) – FDA approved for the treatment of unresectable or metastatic ASPS in **adult and pediatric beneficiaries 2 years of age or older**.
- Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) – FDA approved for the treatment of unresectable or metastatic ASPS in **adult beneficiaries**.

OFF-LABEL USES

Cervical cancer

- The drug is used for the treatment of metastatic carcinoma of the cervix with platinum chemotherapy plus paclitaxel with bevacizumab and atezolizumab (Tecentric).

Colon cancer

- The drug is used in combination with chemotherapy (FOLFOX or CAPEOX) as adjuvant treatment of dMMR/MSI-H colon cancer.

APPROVAL DURATION

Approval is provided for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9022 – Injection, atezolizumab, 10 mg; 10 mg = 1 billable unit
- J9024 – Injection, TECENTRIQ HYBREZA, atezolizumab and hyaluronidase-tqjs, 5 mg

TECVAYLI (TECLISTAMAB-CQYV)

Updated: 05/07/2024

INDICATIONS

- **Multiple myeloma**
  - Tecvayli is indicated for treatment of relapsed or refractory multiple myeloma adult beneficiaries who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

CLINICAL CRITERIA

- The beneficiary has a diagnosis of relapsed or refractory multiple myeloma.
- The drug is prescribed by or in consultation with a hematologist or an oncologist.
- The beneficiary 18 years of age or older.
- Tecvayli is prescribed as monotherapy.
- The beneficiary has received or has documented intolerance to ≥ 4 prior lines of therapy that include all of the following:
  - One proteasome inhibitor (e.g., bortezomib, Kyprolis, Ninlaro)
  - One immunomodulatory agent (e.g., Revlimid, pomalidomide, thalidomide)
  - One anti-CD38 antibody (e.g., Darzalex/Darzalex Faspro, Sarclisa).
- The beneficiary does not have a known active central nervous system (CNS) involvement (e.g., seizure, cerebrovascular ischemia); **OR**
  - The beneficiary exhibits clinical signs of meningeal involvement of multiple myeloma.
- Tecvayli is used as continuation therapy following administration of the first step-up dose, the second step-up dose, and the first treatment dose.
- Tecvayli is available only through a restricted REMS program due to the risk of cytokine release syndrome and neurologic toxicity, including ICANS. Prescribers are enrolled in the Tecvayli REMS program.

DOSAGE AND ADMINISTRATION

Multiple myeloma

- **Step-up dosing schedule** (refer to prescribing information on package insert for recommendations on restarting therapy due to dose delays):
  - **Day 1**: 0.06 mg/kg subcutaneously (first step-up dose)
  - **Day 4**: 0.3 mg/kg subcutaneously (second step-up dose)
    - The second step-up dose may be given between 2 to 4 days after the first step-up dose and may be given up to 7 days after the first step-up dose to allow for resolution of adverse reactions.
  - **Day 7**: 1.5 mg/kg subcutaneously (first treatment dose)
    - The first treatment dose may be given between 2 to 4 days after the second step-up dose and may be given up to 7 days after the second step-up dose to allow for resolution of adverse reactions.

- **Weekly dosing schedule** (refer to prescribing information on package insert for recommendations on restarting therapy due to dose delays.):
  - 1.5 mg/kg subcutaneously once weekly (one week after the first treatment dose and weekly thereafter)
- **Maximum dose**:
  - 1.5 mg/kg per week subcutaneously

APPROVAL DURATION

After the initial hospital administration of three doses (first step-up dose, second step-up dose, and first treatment dose), approval may be provided for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome [ICANS], severe infusion-related reactions, cytokine release syndrome [CRS], hepatotoxicity, neutropenia, infection, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9380 – Injection, teclistamab-cqyv, 0.5 mg = 1 unit

TEPEZZA (TEPROTUMUMAB-TRBW)

Updated: 11/18/2025

INDICATIONS

Tepezza is indicated for treatment of:

- **Thyroid eye disease**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- The drug is prescribed by on in consultation with a specialist in ophthalmology endocrinology, or neuro-ophthalmology
- The beneficiary has a diagnosis of active, moderate to severe Graves orbitopathy with at least one of the following:
  - Lid retraction of ≥ 2 mm
  - Moderate to severe soft tissue involvement
  - Proptosis of ≥ 3 mm above the normal values for race and gender (see table below)
  - Periodic or constant diplopia
- The beneficiary has a baseline clinical activity score (CAS) of at least 4
- The beneficiary is euthyroid OR has mild hypo- or hyperthyroidism

Degree of Proptosis: Upper Limit of Normal for Beneficiaries	
African American Female	23 mm
African American Male	24 mm
White Female	19 mm
White Male	21 mm
Asian Female	16 mm
Asian Male	17 mm

APPROVAL DURATION

Approval is provided for 6 months (maximum of 8 infusions) and may not be renewed

DOSAGE AND ADMINISTRATION

Dosing with 10 mg/kg for first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions

RENEWAL/REAUTHORIZATION

Cannot be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Unclassified biologics

TEZSPIRE (TEZEPELUMAB-EKKO)

Updated: 12/30/2024

INDICATIONS

Tezspire is indicated for the add-on maintenance treatment of severe asthma in adult and pediatric beneficiaries 12 years of age or older.

CLINICAL CRITERIA

- The beneficiary is at least 12 years of age
- The beneficiary must have severe disease
  - **Components of severity for classifying asthma as severe may include any of the following (not all inclusive):**
    - Symptoms throughout the day
    - Nighttime awakenings, often 7 times per week
    - SABA use for symptom control occurs several times per day
    - Extremely limited normal activities
- The drug is prescribed by a board-certified allergy and immunology specialist
- The drug must be used for add-on maintenance treatment in beneficiaries who are regularly receiving both of following:
  - A high dose inhaled corticosteroid
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifier, etc.)
- The drug is not used in combination with anti-IgE or interleukins (i.e., anti-IL4 or anti-IL5)
- The drug is not administered concurrently with live vaccines
- The beneficiary does not have an active or untreated helminth (parasitic) infection
- In the last 12 months, the beneficiary must have had two or more exacerbations requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy)
  - Exacerbation is defined as requiring systemic corticosteroids, an emergency department visit, or hospitalization for asthma
- The requesting provider must submit documentation of baseline measurement of at least one of the following for assessment of the beneficiary's clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, emergency department visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume (FEV1)
- Beneficiaries ≥ 18 years of age must have a pre-bronchodilator FEV1 < 80%
- Beneficiaries < 18 years of age must have a pre-bronchodilator FEV1 < 90%
- The beneficiary has documentation from requesting provider of medical necessity for Tezspire over the preferred medication (i.e., Fasenra) and other therapies outlined in treatment guidelines.

EXCLUSIONS

- The beneficiary has not been compliant with two asthma maintenance medications, including an inhaled corticosteroid, for at least 12 months
- The beneficiary is receiving another asthma immunomodulator
- The beneficiary is a current smoker
- The beneficiary has helminth infections
  - Pre-existing helminth infections should be treated prior to beginning therapy

APPROVAL DURATION

Approval is for six months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Improvement in asthma symptoms or asthma exacerbations, as evidenced by a decrease in one or more of the following:
  - Use of systemic corticosteroids
  - Two-fold or greater decrease in inhaled corticosteroid use over a span of at least 3 days
  - Hospitalizations
  - Emergency department visits
  - Unscheduled visits to healthcare provider
- Improvement from baseline in forced expiratory volume (FEV1)
- Absence of unacceptable toxicity (e.g., helminth infections, severe hypersensitivity reactions, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2356 – Injection, tezepelumab-ekko, 1 mg

TIVDAK (TISOTUMAB VEDOTIN-TFTV)

Updated: 05/09/2024

INDICATIONS

Tivdak is indicated for treatment of:

- **Cervical cancer**

CLINICAL CRITERIA

- The drug is approved for use in adult beneficiaries.
- The drug is indicated for use in beneficiaries with documented recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- Tivdak is prescribed by an oncologist, along with ophthalmologist consultation.
- The beneficiary has had an ophthalmological evaluation at baseline and is adhering to an eye care plan (described below under **Premedication and Required Eye Care**)

EXCLUSIONS

- The beneficiary has active ocular surface disease or a history of cicatricial conjunctivitis.
- The beneficiary has prior Stevens Johnson syndrome.
- The beneficiary has Grade ≥ 2 peripheral neuropathy.
- The beneficiary known coagulation defects, leading to an increased risk of bleeding.

DOSING AND ADMINISTRATION

- Tivdak is administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is:
  - 2 mg/kg (up to a maximum of 200 mg) given as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

PREMEDICATION AND REQUIRED EYE CARE

Note: As ocular adverse events may be less familiar to gynecologic oncology providers, and to help mitigate risk and manage ocular adverse events, adherence to the following eye care plan, along with the incorporation of ophthalmologists into the oncology care team, is recommended.

- **Ophthalmic exam**: Documentation of ophthalmic exam, including visual acuity and slit lamp at baseline, prior to each dose and as clinically indicated.
- **Topical corticosteroid eye drops**: Initial prescription and all renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer the first drop in each eye prior to each infusion. Instruct the beneficiary to continue to administer eye drops in each eye as prescribed for 72 hours after each infusion.
- **Topical ocular vasoconstrictor drops**: Administer in each eye immediately prior to each infusion.
- **Cold packs**: Use cooling eye pads during the infusion of Tivdak
- **Topical lubricating eye drops**: Instruct beneficiaries to administer for the duration of therapy and for 30 days after last dose of Tivdak.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has documented positive clinical response to the drug.
  - Lack of clinical disease progression with no unacceptable drug toxicity is considered a positive clinical response

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9273 – Injection, tisotumab vedotin-tftv, 1 mg; 1 billable unit = 1 mg

TREMFYA (GUSELKUMAB)

Updated: 05/08/2025

INDICATIONS

Tremfya is indicated for the treatment of:

- **Plaque psoriasis**
- **Psoriatic arthritis**
- **Ulcerative colitis**
- **Crohn's disease**

CLINICAL CRITERIA

Plaque psoriasis

- The beneficiary is 18 years of age or older.
- The beneficiary has a documented diagnosis of moderate to severe plaque psoriasis.
- The beneficiary has had a ≥ 6-month trial with at least ONE agent from each of the following (6 months of topical and 6 months of systemic):
  - Topical drug therapy with corticosteroids, calcipotriene, calcitriol, tazarotene, roflumilast, or tapinarof.
  - Systemic drug therapy with methotrexate, acitretin, or cyclosporin.
- The beneficiary must have tried and failed or have a contraindication to phototherapy.
- The beneficiary has previously been treated with a targeted immunomodulator that is FDA-approved for the treatment of plaque psoriasis (e.g., Cimzia [certolizumab], adalimumab, Otezla [apremilast], Skyrizi [Risankizumab], or ustekinumab).
- The beneficiary continues to have symptoms after a trial of conventional therapy and has at least ONE of the following:
  - Involvement of ≥ 10% body surface area (BSA)
  - Psoriasis Area and Severity Index (PASI) score ≥12
  - Plaque location severely impacts quality of life (e.g., head/neck, palms, soles of feet, genitalia)
- Tremfya is prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist in treating plaque psoriasis.

Psoriatic arthritis

- The beneficiary is 18 years of age or older.
- The beneficiary has a documented diagnosis of psoriatic arthritis.
- The beneficiary has had a ≥ 6-month trial of any of the following:
  - Hydroxychloroquine
  - Methotrexate
  - Sulfasalazine
  - Leflunomide

- The beneficiary has previously been treated with a targeted immunomodulator that is FDA-approved for the treatment of psoriatic arthritis (e.g., Cimzia [certolizumab], adalimumab, Simponi [golimumab], ustekinumab, Xeljanz [tofacitinib], Otezla [apremilast], or Rinvoq [upadacitinib]).
- Tremfya is prescribed by or in consultation with a rheumatologist or dermatologist.

Ulcerative colitis (UC)

- The beneficiary is 18 years of age or older.
- The beneficiary has a documented diagnosis of moderate to severe ulcerative colitis, as defined by ONE of the following:
  - Fecal calprotectin > 150 µg/g
  - Endoscopy Mayo subscore ≥ 2 or modified Mayo score (mMS) ≥ 5.
- The beneficiary has been hospitalized for ulcerative colitis OR had a trial and failure of at least two conventional therapies for ulcerative colitis (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or a corticosteroid such as prednisone, methylprednisolone, etc.).
- The beneficiary has previously been treated with a targeted immunomodulator that is FDA-approved for the treatment of ulcerative colitis (e.g., Infliximab [Remicade, biosimilars], Omvoh [mirikizumab-mrkz], risankizumab-rzaa [Skyrizi], Stelara [ustekinumab], etc.)
- Tremfya is prescribed by or in consultation with a gastroenterologist.

Crohn's disease (CD)

- The beneficiary is 18 years of age or older.
- The beneficiary has a documented diagnosis of moderate to severe Crohn's disease confirmed by assessment of stool frequency, abdominal pain score, and Simple Endoscopic Score for Crohn's disease (SES-CD).
- The beneficiary has been hospitalized with Crohn's disease or been diagnosed with a fistula or abscess OR had a trial and failure of at least two conventional therapies for Crohn's disease (e.g., 6-mercaptopurine, azathioprine, methotrexate, or a corticosteroid such as prednisone, methylprednisolone, etc.).
- The beneficiary has previously been treated with a targeted immunomodulator that is FDA-approved for the treatment of Crohn's disease (e.g., Infliximab [Remicade, biosimilars], Omvoh [mirikizumab-mrkz], Skyrizi [risankizumab-rzaa], Stelara [ustekinumab], etc.).
- Tremfya is prescribed by or in consultation with a gastroenterologist.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Plaque psoriasis and psoriatic arthritis:
  - Documentation of disease response with treatment, and the beneficiary does not show evidence of progressive disease while on therapy.
- Ulcerative colitis and Crohn's disease:

- Documentation from the provider of positive beneficiary response to therapy (i.e., endoscopic evidence of mucosal healing).

- Absence of unacceptable toxicity from Tremfya

RECOMMENDED DOSING

- **Plaque psoriasis**
  - 100 mg administered by subcutaneous injection at week 0, week 4, and every 8 weeks thereafter.
- **Psoriatic arthritis**
  - 100 mg administered by subcutaneous injection at week 0, week 4, and every 8 weeks thereafter. Tremfya can be used alone or in combination with a conventional DMARD (e.g., methotrexate).
- **Ulcerative colitis**
  - **Induction**: 200 mg administered by intravenous infusion over at least one hour at week 0, week 4, and week 8.
  - **Maintenance**: 100 mg administered by subcutaneous injection at week 16 and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at week 12 and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.
- **Crohn's disease**
  - **Induction**: 200 mg administered by intravenous infusion over at least one hour at week 0, week 4, and week 8 or 400 mg administered by subcutaneous injection at week 0, week 4, and week 8.
  - **Maintenance**: 100 mg administered by subcutaneous injection at week 16 and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at week 12 and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1628 – Injection, guselkumab, 1 mg

TRODELVY (SACITUZUMAB GOVITECAN-HZIY)

Updated: 09/07/2024

INDICATIONS

Trodelvy is indicated for treatment of:

- **Triple-negative breast cancer (mTNBC)**
- **HR-positive, HER2-negative breast cancer**
- **Metastatic urothelial cancer (mUC)**

CLINICAL CRITERIA

- The beneficiary has confirmed advanced or metastatic triple-negative breast cancer; **OR**
- The beneficiary has confirmed advanced or metastatic HR-positive, HER2-negative breast cancer; **OR**
- The beneficiary has confirmed advanced or metastatic urothelial cancer (mUC)
- The beneficiary has documented Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1.
  - Recent performance status must be documented. The requested drug is considered investigational for beneficiaries with poor performance status because studies excluded them.

Metastatic triple-negative breast cancer

- The drug is prescribed by an oncologist.
- The beneficiary has unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) and has previously received two or more prior systemic therapies, at least one of which was for metastatic disease.

HR-positive, HER2-negative breast cancer

- The drug is used for treatment of unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC2+/ISH-) breast cancer in beneficiaries who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
- **Note regarding ICH**: ICH is the common test to determine whether or not the cancer cells have HER2 receptors or hormone receptors on their surface. In current practice, IHC scores of 0, 1+, and 2+/ISH- are clinically classified as HER2-negative.

Metastatic urothelial cancer

- The drug is prescribed by an oncologist.
- The beneficiary has locally advanced or metastatic urothelial cancer (mUC) and has previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

NCCN RECOMMENDED INDICATIONS

- **HR-negative, HER2-negative (triple-negative) breast cancer**
  - The drug is used as second-line monotherapy in beneficiaries with recurrent unresectable HR-negative, HER2-negative TNBC.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary is responding positively to therapy (e.g., decrease in tumor size or spread, reduction, no disease progression, etc.).
- Continue treatment until disease progression or unacceptable toxicity.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9317 – Injection, sacituzumab govitecan-hziy, 2.5 mg; 1 billable unit = 2.5 mg

TYSABRI (NATALIZUMAB), TYRUKO (NATALIZUMAB-SZTN)

Updated: 07/02/2024

INDICATIONS

- **Multiple sclerosis (MS)**: Indicated as monotherapy for the treatment of relapsing forms of MS in adults, including:
  - Clinically isolated syndrome
  - Relapsing-remitting disease
  - Active secondary progressive disease (SPMS)
- **Crohn's disease (CD)**: Indicated for inducing and maintaining clinical response and remission of moderately to severely active CD with evidence of inflammation in adult beneficiaries who have had an inadequate response to or are unable to tolerate conventional CD therapies and inhibitors of TNF-α.

CLINICAL CRITERIA

Multiple sclerosis (MS)

- The beneficiary has a diagnosis of one of the following clinical subtypes of multiple sclerosis:
  - Clinically isolated syndrome
  - Relapsing-remitting multiple sclerosis
  - Active secondary progressive multiple sclerosis
- The beneficiary is 18 years of age or older
- Natalizumab products are not prescribed or administered concurrently with other disease-modifying therapies for multiple sclerosis (with the exception of dalfampridine)
- The drug is prescribed by or in consultation with a neurologist.

Crohn's disease (CD)

- The beneficiary has a diagnosis of moderate to severe Crohn's disease (CD)
- The beneficiary is 18 years of age or older.
- The beneficiary has documentation of failure after a minimum consecutive 90-day trial of at least one immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless clinically adverse effects are experienced or all immunomodulators are contraindicated.
- The beneficiary has documentation of failure after a minimum consecutive 90-day trial of at least one TNF-α inhibitor therapy (adalimumab [Humira or biosimilar], certolizumab [Cimzia], infliximab [Remicade or biosimilar]), unless clinically adverse effects are experienced or all TNF-α inhibitors are contraindicated.
- Natalizumab products are not prescribed concurrently with other immunomodulators (e.g., azathioprine, 6-MP, MTX) or TNF-α inhibitors.
- Prescribed by or in consultation with a gastroenterologist.

BLACK BOX WARNING

Natalizumab products increase the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include the presence of anti-JCV (John Cunningham virus) antibodies, duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment.

APPROVAL DURATION

- **Multiple sclerosis**: If the above criteria are met, authorization of Natalizumab products will be approved for 6 months. Subsequent authorization will be based on therapeutic benefit as documented by the physician.
- **Crohn's disease**: If the above criteria are met, authorization of Natalizumab products will be approved for 3 months. Subsequent authorization will be based on therapeutic benefit as documented by the physician.
  - **Note**: Per FDA-approved label, if a beneficiary with CD has not experienced therapeutic benefit by 12 weeks of induction therapy, natalizumab products should be discontinued.
  - For beneficiaries with CD who start a natalizumab product while on chronic oral corticosteroids, commence steroid tapering as soon as a therapeutic benefit of the natalizumab product has occurred; if the beneficiary with CD cannot be tapered off of oral corticosteroids within 6 months of starting natalizumab product, discontinue natalizumab product.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- **Multiple sclerosis (MS)**: Documentation of stabilization or positive response to treatment with a natalizumab product, demonstrated by efficacy evidenced by ANY of the following:
  - A decrease in frequency and severity of sequelae relapses from baseline
  - Beneficial effect on MRI measures of disease severity
  - Improvement in beneficiary's reported MS related symptoms
- **Crohn's disease (CD)**: Documentation of remission of disease or improved disease activity.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J2323 Tysabri (natalizumab)

TZIELD (TEPLIZUMAB-MZWV)

Updated: 11/28/2023

INDICATIONS

Tzield is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric beneficiaries 8 years of age or older with Stage T1D.

CLINICAL CRITERIA

- The beneficiary is at least 8 years of age.
- The beneficiary does not have a clinical history of type 2 diabetes (T2D).
- The beneficiary has at least one relative with a diagnosis of T1D.
- The beneficiary has a diagnosis of stage 2 T1D confirmed by the following:
  - The beneficiary has documentation of at least two positive pancreatic islet autoantibodies from the following:
    - Islet cell autoantibody (ICA)
    - Insulinoma-associated antigen-2 autoantibody (IA-2A)
    - Insulin autoantibody (IAA)
    - Zinc transporter 8 autoantibody (ZnT8a)
    - Glutamic acid decarboxylase 65 (GAD65) autoantibody
  - The beneficiary has documentation of dysglycemia without overt hyperglycemia using an oral glucose tolerance test or other appropriate test for dysglyemia, defined as:
    - Fasting plasma glucose ≥ 100 mg/dL and < 126 mg/dL; **OR**
    - 2-hour post-prandial plasma glucose level ≥ 140 mg/dL and < 200 mg/dL; **OR**
    - A1C ≥ 5.7 and < 6.5% or ≥ 10% increase in A1C
- The beneficiary has not received prior therapy with teplizumab.
- The provider must obtain a complete blood count and liver enzyme tests prior to the start of treatment.
  - **Note**: teplizumab-mzwv (Tzield) is not recommended for beneficiaries with lab abnormalities in lymphocytes, hemoglobin, platelets, absolute neutrophil count, and liver function tests.
- The provider must assess the beneficiary's history of chronic infection and monitor for any signs of serious infections while on teplizumab-mzwv. If a serious infection develops, teplizumab-mzwv therapy should be discontinued.

EXCLUSIONS

The use of teplizumab-mzwv (Tzield) is not approved for beneficiaries with T2D or any other stages of T1D other than stage 2 T1D.

APPROVAL DURATION

Approval is for 14 doses and may not be renewed.

RECOMMENDED DOSAGE AND ADMINISTRATION

Administer TZIELD by intravenous infusion over a minimum of 30 minutes using a body surface area-based dosing, once daily for 14 consecutive days, as follows:

- Day 1: 65 mcg/m^2
- Day 2: 125 mcg/m^2
- Day 3: 250 mcg/m^2
- Day 4: 500 mcg/m^2
- Days 5 through 14: 1,030 mcg/m^2

Do not administer two doses on the same day.

RENEWAL/REAUTHORIZATION

May not be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9381 – Injection, teplizumab-mzwv, 5 mcg; 1 billable unit = 5 mcg

ULTOMIRIS (RAVULIZUMAB-CWVZ)

Updated: 03/26/2024

INDICATIONS

Ultomiris is indicated for treatment of adult and pediatric beneficiaries with:

- **Paroxysmal nocturnal hemoglobinuria (PNH)**
- **Atypical hemolytic uremic syndrome (aHUS)**
- **Generalized myasthenia gravis (gMG)**
- **Neuromyelitis optica spectrum disorder (NMOSD)**

CLINICAL CRITERIA

Paroxysmal nocturnal hemoglobinuria (PNH)

- The beneficiary is one month of age or older
- The diagnosis must be accompanied by detection of PNH clones of at least 5% by flow cytometry diagnostic testing:
  - The presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) must be demonstrated within at least 2 different cell lines (granulocytes, monocytes, erythrocytes)
- The beneficiary has one of the following indications for therapy:
  - Presence of a thrombotic event
  - Presence of organ damage secondary to chronic hemolysis
  - The beneficiary is pregnant, and potential benefit outweighs potential fetal risk
  - The beneficiary is transfusion dependent
  - The beneficiary has high lactate dehydrogenase (LDH) activity (defined as $\geq$ 1.5 x ULN) with clinical symptoms
- Documented baseline values have been obtained for one or more of the following (necessary for renewal):
  - Serum lactate dehydrogenase (LDH)
  - Hemoglobin level
  - Packed RBC transfusion requirement

Atypical hemolytic uremic syndrome (aHUS)

- The drug must be prescribed by or in consultation with a hematologist or nephrologist
- The beneficiary is 1 month of age or older
- The beneficiary shows signs of thrombotic microangiopathy (TMA)
- Thrombotic thrombocytopenia purpura (TTP) has been ruled out by evaluating ADAMTS-13 level
- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out
- Documented baseline values have been obtained for one or more of the following (necessary for renewal):
  - Serum lactate dehydrogenase (LDH)

- Serum creatinine/eGFR
- Platelet count
- Plasma exchange/infusion requirement

Generalized myasthenia gravis

- The beneficiary is an adult 18 years of age or older.
- The prescribing physician is a neurologist.
- The beneficiary has a documented diagnosis of generalized Myasthenia Gravis.
- The beneficiary has documentation of a positive serologic test for anti-acetylcholine antibodies.
- The beneficiary has documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis.
- The beneficiary has documentation of baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 5.
- The beneficiary has documented trial and failure or contraindication to 2 or more conventional therapies (e.g., acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies).

Neuromyelitis optica spectrum disorder

- Adult beneficiaries 18 years of age or older have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD), as confirmed by ANY 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
- Diagnosis of multiple sclerosis (MS) or other diagnoses that can mimic NMOSD have been ruled out.
- The drug is prescribed by or in consultation with a neurologist.

EXCLUSIONS

- The beneficiary does not have a systemic infection (life-threatening meningococcal infections/sepsis have occurred in beneficiaries treated with Ultomiris)
- Ultomiris is not prescribed or used in combination with other immunomodulatory biologic therapies (e.g., rituximab [Rituxan], eculizumab [Soliris], efgartigimod alfa-fcab [Vyvgart], satralizumab [Enspryng], inebilizumab [Uplizna] etc.)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections [septicemia or meningitis], infusion reactions, serious infections, thrombotic microangiopathy complications [TMA], etc.)
- Disease response, as indicated by one or more of the following:
  - Paroxysmal Nocturnal Hemoglobinuria (PNH)
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization or improvement in hemoglobin level from pretreatment baseline
    - Decrease in packed RBC transfusion requirement from pretreatment baseline
  - aHUS
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization or improvement in hemoglobin level from pretreatment baseline
    - Increase in platelet count from pretreatment baseline
  - gMG
    - The beneficiary has experienced a documented therapeutic response, as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.
  - NMOSD
    - The beneficiary has a documented positive clinical response from baseline, as demonstrated by reduction in the signs and symptoms of NMOSD or reduction in the number or severity of relapses.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1303 – Injection, ravulizumab-cwvz, 10 mg; 1 billable unit = 10 mg

UPLIZNA (INEBILIZUMAB-CDON)

Updated: 07/29/2025

INDICATIONS

Uplizna is indicated for treatment of:

- **Neuromyelitis optica spectrum disorder (NMOSD)**
- **Immunoglobulin G4-related disease (IgG4-RD)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and is confirmed negative for active HBV.
- The beneficiary has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment.
- The beneficiary's serum immunoglobulin baseline will be measured prior to the start of therapy.

Neuromyelitis optica spectrum disorder (NMOSD)

- The beneficiary is anti-aquaporin-4 (AQP4) positive.
- The beneficiary is diagnosed with neuromyelitis optica spectrum disorder (NMOSD), as confirmed by ANY 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
- Diagnosis of multiple sclerosis (MS) or other diagnoses that can mimic NMOSD have been ruled out.
- The drug must be prescribed by or in consultation with a neurologist.

Immunoglobulin G4-related disease (IgG4-RD)

- The beneficiary has a confirmed diagnosis of IgG4-related disease.
- The beneficiary is experiencing (or recently experienced) an IgG4-RD flare requiring corticosteroid treatment; **AND**
  - The beneficiary has disease that is refractory to corticosteroids; **OR**
  - The beneficiary has a contraindication or intolerance to corticosteroid treatment.
- The beneficiary is at high risk of recurrent disease flares on a history of disease in ≥ 2 organs or sites.

CONTRAINDICATIONS

- Previous life-threatening reaction to infusion of Uplizna
- Active hepatitis B infection
- Active or untreated latent tuberculosis

DOSAGE AND ADMINISTRATION

Uplizna is administered as an intravenous infusion, as follows:

- **Initial dose**: 300 mg IV infusion followed 2 weeks later by a second 300 mg IV infusion.
- **Subsequent doses** (starting 6 months from the first infusion): Single 300 mg IV infusion every 6 months.
- **Maximum dose** (1 billable unit = 1 mg): 300 units on days 1 and 15, then 300 units every 6 months thereafter

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., serious or life-threatening infusion related reactions, serious infections, including progressive multifocal leukoencephalopathy [PML], hypogammaglobulinemia requiring IVIG treatment or leading to recurrent infections, etc.).

Neuromyelitis optica spectrum disorder (NMOSD)

- Disease response, as indicated by stabilization/improvement in one or more of the following:
  - Neurologic symptoms, as evidenced by a decrease in acute relapses, improvement in stability, or improvement in EDSS
  - Reduced hospitalizations
  - Reduction/discontinuation in plasma exchange treatments

Immunoglobulin G4-related disease (IgG4-RD)

- Disease response, as indicated by one or more of the following:
  - Reduction in corticosteroid requirement for IgG4-RD flare treatment from baseline
  - Reduction in IgG4-RD flares from baseline
  - Stabilization/improvement in symptoms, physical exam findings, imaging results, laboratory tests, or pathological findings in IgG4-RD involved organ/sites compared to baseline

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1823 – Injection, inebilizumab-cdon, 1 mg; 1 billable unit = 1 mg

VABYSMO (FARICIMAB-SVOA)

Updated: 07/17/2024

INDICATIONS

Vabysmo is indicated for treatment of:

- **Neovascular (wet) age-related macular degeneration (nAMD)**
- **Diabetic macular edema (DME)**
- **Macular edema following retinal vein occlusion (RVO)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- Vabysmo must be prescribed by an ophthalmologist
- The beneficiary must have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD), diabetic macular edema (DME), or macular edema following retinal vein occlusion (RVO)

DOSAGE AND ADMINISTRATION

Neovascular (wet) age-related macular degeneration (nAMD)

- The recommended dose for Vabysmo is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens:
  - Weeks 28 and 44; **OR**
  - Weeks 24, 36, and 48; **OR**
  - Weeks 20, 28, 36, and 44
- Some beneficiaries may need every-4-week (monthly) dosing after the first 4 doses. Beneficiaries should be assessed regularly.

Diabetic macular edema (DME)

- Vabysmo is recommended to be dosed by following one of these two dose regimens:
  - 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses.
    - If after at least 4 doses resolution of edema is achieved (based on the central subfield thickness [CST] of the macula as measured by optical coherence tomography), then the interval of dosing may be modified by extensions of up to 4-week interval increments or reductions of up to 8-week interval increments based on CST and visual acuity evaluations; **OR**
  - 6 mg can be administered every 4 weeks for the first 6 doses, followed by 6 mg via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks.
- Some beneficiaries may need every-4-week (monthly) dosing after the first 4 doses. Beneficiaries should be assessed regularly.

Macular edema following retinal vein occlusion (RVO)

- The recommended dose for Vabysmo is 6 mg (0.05 mL of 120 mg/mL) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for 6 months.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of ongoing drug benefit to the beneficiary in terms of improvement or stability in disease state or condition

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Faricimab-svoa Injection, for intravitreal use

VECTIBIX (PANITUMUMAB)

Updated: 01/17/2025

INDICATIONS

Vectibix is indicated for the treatment of:

- **Adult beneficiaries with wild-type RAS (defined as wild-type in both KRAS and NRAS) metastatic colorectal cancer (mCRC)**
  - **Note**: According to the National Cancer Institute, "**wild-type**" is a term used to describe a gene when it is found in its natural, non-mutated (unchanged) form (i.e., a genetic finding indicating that RAS family gene mutations are absent in a sample).
- **KRAS G12C-mutated metastatic colorectal cancer (mCRC)***

CLINICAL CRITERIA

Adult beneficiaries with wild-type RAS (defined as wild-type in both KRAS and NRAS) metastatic colorectal cancer (mCRC)

- The beneficiary is 18 years or older and has progressive, metastatic disease.
- The beneficiary is both KRAS and NRAS mutation negative (wild-type), as determined by an FDA-approved test.
- The drug is used as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.
- The drug is used in combination with FOLFOX for first-line treatment
- The drug is used in combination with FOLFIRI as second-line treatment

KRAS G12C-mutated metastatic colorectal cancer (mCRC)

- The drug is used in combination with sotorasib (Lumakras) for the treatment of KRAS G12C-mutated mCRC in adult beneficiaries with who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

LIMITATIONS OF USE (EXCLUSIONS)

- Vectibix is not indicated for the treatment of beneficiaries with RAS-mutant metastatic colorectal cancer, unless used in combination with sotorasib (Lumakras) in KRAS G12C-mutated mCRC.
- Vectibix is not indicated for the treatment of mCRC in beneficiaries for whom RAS mutation status is unknown.

APPROVAL DURATION

Authorization is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

- Absence of unacceptable toxicity from the drug (e.g., dermatologic/soft-tissue toxicity, electrolyte depletion, severe infusion-related reactions, acute renal failure, pulmonary fibrosis/interstitial lung disease [ILD], keratitis, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9303 – Injection, panitumumab, 10 mg; 1 billable unit = 10 mg

VELCADE (BORTEZOMIB), BORTEZOMIB GENERICS

Updated: 09/19/2025

INDICATIONS

Velcade / Bortezomib generics are FDA indicated for:

- **Multiple myeloma**
- **Mantle cell lymphoma**

COMPENDIA RECOMMENDED INDICATIONS

NCCN Compendium for Velcade / Bortezomib generics (bortezomib)

Systemic light chain amyloidosis

- For beneficiaries with newly diagnosed disease, or if the drug is used as repeat initial therapy and the beneficiary has been relapse-free for several years; **AND**
  - The drug is used as a single agent; **OR**
  - The drug is used in combination with dexamethasone with or without melphalan or lenalidomide; **OR**
  - The drug is used in combination with dexamethasone and cyclophosphamide; **OR**
  - The drug is used in combination with daratumumab and hyaluronidase-fihj, cyclophosphamide, and dexamethasone
- For beneficiaries with relapsed or refractory disease; **AND**
  - The drug is used as a single agent; **OR**
  - The drug is used in combination with dexamethasone with or without melphalan

Waldenstrom's macrogloblinemia/lymphoplasmacytic lymphoma

- The drug is used as a single agent; **OR**
  - The drug is used in combination with dexamethasone; **OR**
  - The drug is used in combination with rituximab with or without dexamethasone

Multicentric Castleman's disease

- The drug must be used as subsequent therapy; **AND**
- The beneficiary has relapsed/refractory or progressive disease; **AND**
- The drug is used as a single agent or in combination with rituximab

Adult T-cell leukemia/lymphoma

- The drug must be used as a single agent for acute disease or lymphoma; **AND**
- The drug is used as subsequent therapy for beneficiaries who did not respond to first-line therapy for acute disease or lymphoma subtypes

Acute lymphoblastic leukemia (ALL) – Adult

- The drug is used in combination with chemotherapy; **AND**
- The beneficiary has Philadelphia (Ph) chromosome negative T-cell disease

Acute lymphoblastic leukemia (ALL) – Pediatric

- The beneficiary is at least 1 year of age
- The drug is used as a component of the COG ALL07P1 regimen (bortezomib, vincristine, doxorubicin, pegaspargase, prednisone); **AND**
  - The beneficiary has Philadelphia (Ph) chromosome negative B-cell disease
  - The drug is used in combination with dasatinib or imatinib for Philadelphia (Ph) chromosome positive B-cell disease
- The beneficiary has T-cell disease
  - The drug is used in combination with a corticosteroid (e.g., prednisone or dexamethasone), vincristine, doxorubicin, and pegaspargase

Kaposi sarcoma

- The drug is used as subsequent therapy for relapsed or refractory disease
- The beneficiary has advanced cutaneous, oral, visceral, or nodal disease
- The beneficiary has progressed on or not responded to first-line therapy
- The beneficiary has progressed on alternate first-line therapy
  - The drug is used as a single agent in beneficiaries without human immunodeficiency virus (HIV)
  - The drug is used in combination with antiretroviral therapy for beneficiaries with HIV

Primary cutaneous CD30+ T-cell lymphoproliferative disorders

- The drug is used as a single agent; **AND**
- The beneficiary has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
  - The beneficiary has cutaneous ALCL with regional nodes (excludes systemic ALCL)

Pediatric Hodgkin lymphoma

- The drug is used for relapsed or refractory disease in combination with ifosfamide and vinorelbine
- **Note**: Beneficiaries with pediatric Hodgkin lymphoma may include certain adolescent and young adult (AYA) beneficiaries up to 39 years of age.

Antibody-mediated rejection (AMR) in cardiac transplantation

- The beneficiary is a pediatric or adult heart transplant recipient
- The drug is used as a secondary therapy for AMR after trial and failure of IVIg, plasmapheresis, anti-lymphocyte antibodies, or high-dose corticosteroids.

Antibody-mediated rejection (AMR) in kidney transplantation

- The beneficiary is a pediatric or adult kidney transplant recipient
- The drug is used as a secondary therapy for AMR after trial and failure of IVIg, plasmapheresis, anti-lymphocyte antibodies, or high-dose corticosteroids.

EXCLUSION

Velcade is **not** approved for the following conditions:

- Colorectal cancer
- Malignant melanoma
- Non-cutaneous peripheral T-cell lymphoma (PTCL)

- Non-small cell lung cancer
- Other lymphomas (not otherwise listed)
- Prostate cancer
- Renal cell carcinoma

Note: In May 2022, the FDA granted approval for eight generic versions of Takeda's Velcade. The generic products are approved in the form of single-use vials containing 3.5 mg bortezomib for IV or subcutaneous administration. The FDA considers these newly approved products to be therapeutically equivalent to Velcade.

In addition to use in MM and MCL, the NCCN guidelines support bortezomib therapy (with a category 1 or 2A recommendation) for treatment of adult and pediatric acute lymphoblastic leukemia (ALL), adult T-cell leukemia/lymphoma, Kaposi sarcoma, multicentric Castleman's disease, pediatric Hodgkin lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, systemic light chain amyloidosis, and Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g. peripheral neuropathy, hypotension, cardiac toxicity, pulmonary toxicity, posterior reversible encephalopathy syndrome, gastrointestinal toxicity, thrombocytopenia, neutropenia, tumor lysis syndrome, hepatic toxicity, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9041 – Injection, bortezomib (Velcade), 0.1 mg; 1 billable unit = 0.1 mg
- J9044 – Injection, bortezomib, not otherwise specified, 0.1 mg; 1 billable unit = 0.1 mg
- J9046 – Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to J9041, 0.1 mg.
- J9048 – Injection, bortezomib (fresenius kabi), not therapeutically equivalent to J9041, 0.1 mg
- J9049 – Injection, bortezomib (hospira), not therapeutically equivalent to J9041, 0.1 mg

VIDAZA (AZACITIDINE)

Updated: 05/28/2024

INDICATIONS

Vidaza is indicated for treatment of:

- **Myelodysplastic syndrome (MDS) subtypes:**
  - **Refractory anemia or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions)**
  - **Refractory anemia with excess blasts (RAEB)**
  - **Refractory anemia with excess blasts in transformation (RAEB-T)**
  - **Chronic myelomonocytic leukemia (CMMoL)**
- **Juvenile myelomonocytic leukemia (JMML)** – Includes pediatric beneficiaries 1 month of age or older.

OFF-LABEL USES

- **Acute myeloid leukemia**
- **Myelofibrosis (MF)**

APPROVAL DURATION

Approval is for 6 months and is eligible for renewal.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., severe cytopenia [anemia, neutropenia and thrombocytopenia], severe hepatic and renal toxicities, tumor lysis syndrome, etc.)
- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9025 – Injection, azacitidine, 1 mg: 1 billable unit = 1 mg

VILTEPSO (VILTOLARSEN)

Updated: 05/28/2024

INDICATIONS

Viltepso has FDA approval for:

- **Duchenne muscular dystrophy (DMD)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of Duchenne muscular dystrophy (DMD) by or in consultation with a neurologist with expertise in the diagnosis of DMD
- Medical records have been submitted confirming by testing that the mutation of the DMD gene is amenable to amenable to exon 53 skipping
- The beneficiary has been on a stable dose of oral corticosteroids, unless contraindicated or intolerant, for at least 3 months
- The beneficiary is not concurrently being treated with other DMD antisense oligonucleotides (e.g., casimersen [Amondys 45], golodirsen [Vyondys 53], or eteplirsen [Exondys 51]).
- The beneficiary has baseline documentation within the last 30 days of the following:
  - Pulmonary function test (PFT)
  - End-tidal capnography (ETCo2)
  - Timed 30-foot walk
  - Time to go up 4 stairs
  - Brook scale for upper extremity
  - Vignos scale for lower extremity

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., renal toxicity/proteinuria, etc.)
- Follow-up functional test results must show stabilization or improvement of beneficiary function compared to baseline measures.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3490 – Unclassified drugs; Injection, viltolarsen, 1 mg; 1 billable unit = 1 mg

VIMIZIM (ELOSULFASE ALFA)

Updated: 03/28/2024

INDICATIONS

Vimizim is indicated for treatment of:

- **Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)**

CLINICAL CRITERIA

Mucopolysaccharidosis (MPS IVA, Morquio A Syndrome)

- The beneficiary is 5 years of age or older
- The beneficiary has a documented diagnosis of Mucopolysaccharidosis IVA with biochemical/genetic confirmation by one of the following:
  - Absence or marked reduction in N-acetylgalactosamie 6-sulfatase enzyme activity; **OR**
  - Sequence analysis or depletion/duplicative analysis of the N-acetylgalactosamie 6-sulfatase gene for biallelic mutation
- Documented baseline six-minute walk test (6-MWT).

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has shown a response to therapy, as evidenced by one or more of the following markers when compared to pretreatment baseline values:
  - Stability or improvement on endurance tests
  - Stability or improvement in pulmonary function tests
- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis/hypersensitivity reactions, acute respiratory complications, spinal/cervical cord compression, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1322 – Vimizim (Biomarin Pharmaceutical) 5 mg injection; 1 billable unit = 1 mg

VPRIV (VELAGLUCERASE ALFA)

Updated: 10/23/2024

INDICATIONS

VPRIV is indicated for treatment of:

- **Gaucher disease Type 1**

CLINICAL CRITERIA

Type 1 Gaucher's disease

- **Pediatric guidelines**
  - The beneficiary is at least 4 years of age
  - The beneficiary has a documented diagnosis of Type 1 Gaucher disease, as confirmed by reduced glucocerebrosidase activity in peripheral leukocytes
- **Adults only guidelines (the beneficiary is 18 years of age or older)**:
  - The beneficiary's disease results in one or more of the following:
    - Anemia (hemoglobin ≤ 11 g/dL [women] or 12 g/dL [men]); **OR**
    - Moderate to severe hepatomegaly (liver size ≥ 1.25 times normal) or splenomegaly (spleen size ≥ 5 times normal); **OR**
    - Skeletal disease (e.g., lesions, remodeling defects or deformity of long bones, osteopenia/osteoporosis, etc.); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.); **OR**
    - Thrombocytopenia (platelet count ≤ 120,000/mm^3); **AND**
  - The drug must be used as a single agent.

DOSAGE AND ADMINISTRATION

Administration should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions, including anaphylaxis.

APPROVAL DURATION

Approval is for 12 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response, as indicated by one or more of the following compared to pre-treatment baseline:
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distention, diminished quality of life, etc.)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobinemia
  - Improvement in platelet counts

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3385 – Injection, velaglucerase alfa, 100 units; 1 billable unit = 100 units

VYEPTI (EPTINEZUMAB-JJMR)

Updated: 01/09/2024

INDICATIONS

Vyepti is indicated for the prophylaxis of:

- **Migraine headaches**

CLINICAL CRITERIA

Initial requests for Vyepti (eptinezumab) may be approved when the following are met:

- The beneficiary is 18 years of age or older.
- The beneficiary has migraines ≥ 7 days per month without aura or migraine with visual sensory, speech, or language retinal or brainstem aura.
- The beneficiary has documented history of migraines for ≥ 12 months and was prescribed and is taking a triptan (e.g., Almotriptan [Axert], Eletriptan [Relpax], Frovatriptan [Frova], Naratriptan [Amerge], Rizatriptan [Maxalt], Sumatriptan [Imitrex], Zolmitriptan [Zomig]), unless contraindicated or intolerant (e.g., documented allergic reaction to a triptan).
- The beneficiary is using Vyepti for migraine prophylaxis.
- The beneficiary has had a trial of and inadequate response or intolerance to two agents for migraine headache (at least one agent in any of the following classes) or has a contraindication to all of the following medications:
  - The following antidepressants: amitriptyline and venlafaxine; **OR**
  - One of the following beta blockers: metoprolol, propranolol, timolol (oral), nadolol, atenolol, or nebivolol; **OR**
  - The following calcium channel blocker: verapamil
  - One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, or gabapentin; **OR**
  - Botox (for chronic migraine)
- The beneficiary is not on concurrent preventative treatment with another CGRP ainhibitor.

APPROVAL DURATION

Initial request is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
- The beneficiary has obtained a clinical benefit from Vyepti considered significant by the beneficiary or the prescriber.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3032 – Injection, eptinezumab-jjmr, 1 mg

VYLOY (ZOLBETUXIMAB-CLZB)

Updated: 12/05/2024

INDICATIONS

Gastric or gastroesophageal junction adenocarcinoma

CLINICAL CRITERIA

- The beneficiary is an adult 18 years of age or older.
- The beneficiary has a diagnosis of:
  - Locally advanced unresectable or metastatic human epithelial growth factor receptor 2 (HER2)-negative gastric; **OR**
  - Gastroesophageal junction adenocarcinoma for which tumors are claudin (CLDN) 18.2 positive.
- Vyloy is prescribed in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment.
- Vyloy is prescribed by or in consultation with an oncologist.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation of tumor response with stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of hypersensitivity reactions, including serious anaphylaxis reactions.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3490 – Unclassified drugs
- J3590 – Unclassified biologics
- J9999 – Not otherwise classified antineoplastic drugs
- C9399 – Unclassified drugs or biologics

VYONDYS 53 (GOLODIRSEN)

Updated: 07/02/2024

INDICATIONS

Vyondys 53 is FDA approved for:

- **Duchenne muscular dystrophy (DMD)**

CLINICAL CRITERIA

- The beneficiary has a diagnosis of Duchenne muscular dystrophy (DMD) by or in consultation with a neurologist with expertise in the diagnosis of DMD
- Medical records have been submitted confirming that the mutation of the DMD gene is amenable to exon 53 skipping
- The beneficiary has been on a stable dose of oral corticosteroids, unless contraindicated or intolerant, for at least 3 months
- The beneficiary is not concurrently treated with other DMD antisense oligonucleotides (e.g., casimersen [Amondys 45], viltolarsen [Viltepso], or eteplirsen [Exondys 51]).
- The beneficiary has baseline documentation within the last 30 days of the following:
  - Pulmonary function test (PFT)
  - End-tidal capnography (ETCo2)
  - Timed 30-foot walk
  - Time to go up 4 stairs
  - Brooke scale for upper extremity
  - Vignos scale for lower extremity

APPROVAL DURATION

Approval is for 6 months at a time

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., renal toxicity/proteinuria, etc.)
- Follow-up functional test results must show stabilization or improvement of beneficiary function compared to baseline measures.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J1429 – Injection, golodirsen, 10 mg

VYVGART (EFGARTIGIMOD ALFA-FCAB)

Updated: 01/19/2024

INDICATIONS

Vyvgart is indicated for treatment of:

- **Generalized myasthenia gravis (gMG)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The beneficiary has a documented diagnosis of anti-acetylcholine receptor antibody-positive (AChR-Ab+) generalized myasthenia gravis (gMG).
- The beneficiary has Myasthenia Gravis Foundation of America (MGFA) clinical classification Class II to IV.
- The beneficiary has documentation of baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 5.
- The prescribing physician is a neurologist or rheumatologist.
- Vyvgart is not being prescribed concurrently with other immunomodulatory biologic therapies (e.g., rituximab [Rituxan], eculizumab [Soliris], ravulizumab [Ultomiris], satralizumab [Enspryng], inebilizumab [Uplizna] etc.).

RECOMMENDED DOSE AND DOSING SCHEDULE

The recommended dose of Vyvgart (efgartigimod alfa-fcab) is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks.

APPROVAL DURATION

Initial approval of Vyvgart is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that the beneficiary has experienced a therapeutic response, as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9332 – Injection, efgartigimod alfa-fcab, 2 mg; 1 billable unit = 2 mg

VYXEOS (DAUNORUBICIN AND CYTARABINE)

Updated: 07/02/2024

INDICATIONS

Vyxeos is indicated for treatment of:

- **Newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric beneficiaries 1 year of age or older**

CLINICAL CRITERIA

- Vyxeos is prescribed by a hematology or oncology specialist with experience in the treatment of AML or other types of blood cancer.
- Baseline left ventricular ejection fraction (LVEF) is within normal limits and will be reassessed as clinically required.
- Vyxeos is not used in combination with other chemotherapy.
- The beneficiary has a diagnosis of one of the following sub-types of disease:
  - Therapy-related acute myeloid leukemia (t-AML)
  - AML with myelodysplasia-related changes (AML-MRC)

APPROVAL DURATION

Note: Vyxeos is given in 2 phases: induction and consolidation. A full Vyxeos treatment course can consist of up to 2 cycles of induction and up to 2 cycles of consolidation

- Approval is for a maximum of 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) within 6 months.

RENEWAL/REAUTHORIZATION

May not be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9153 − Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine

XEOMIN (INCOBOTULINUMTOXINA)

Updated: 07/02/2024

INDICATIONS

Xeomin is indicated for treatment of:

- **Chronic sialorrhea**
  - The beneficiary is 2 years of age or older
  - The beneficiary has a diagnosis of chronic sialorrhea
- **Upper limb spasticity in adults**
  - The drug is used to decrease the severity of increased muscle tone which interferes with function or is likely to lead to joint contracture with growth.
  - Upper limb spasticity includes elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus)
  - Spasticity may be due to an injury to the brain or spinal cord or it may accompany a neurological disorder (e.g., stroke, traumatic brain injury [TBI], multiple sclerosis [MS], spinal cord injury [SCI], cerebral palsy [CP])
- **Upper limb spasticity in pediatric beneficiaries**
  - The beneficiary is 2 years of age or older
  - The beneficiary has a diagnosis of upper limb spasticity
  - Spasticity may be due to an injury to the brain or spinal cord or it may accompany a neurological disorder (e.g., stroke, traumatic brain injury [TBI], multiple sclerosis [MS], spinal cord injury [SCI])
- **Cervical dystonia**
  - The beneficiary is 18 years of age or older.
  - The beneficiary has a diagnosis of cervical dystonia.
- **Blepharospasm**
  - The beneficiary is 18 years of age or older.
  - The beneficiary has a diagnosis of blepharospasm.
- **Glabellar lines**
  - The beneficiary is 18 years of age or older.
  - The beneficiary has a diagnosis of moderate to severe glabellar lines with corrugator or procerus muscle activity.

LITERATURE SUPPORTED INDICATIONS

- **Overactive bladder**
  - The beneficiary has symptoms of urinary incontinence, urgency, and frequency
  - The beneficiary has tried and failed a medication from either antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, or trospium) or beta-adrenergic (e.g., mirabegron) classes.
- **Detrusor overactivity associated with a neurologic condition**

- The beneficiary has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing.
- The beneficiary has tried and failed a medication from either antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, or trospium) or beta-adrenergic (e.g., mirabegron) classes.

- **Severe primary axillary hyperhidrosis**
  - The beneficiary is 18 years of age or older.
  - The beneficiary has a diagnosis of severe primary axillary hyperhidrosis.
  - The beneficiary 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 changing of clothing, difficulty in relationships or social gatherings, etc.)

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- A clinical response is documented with therapy

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0588 – Injection, incobotulinumtoxinA, 1 unit; 1 billable unit = 1 unit

XOLAIR (OMALIZUMAB)

Updated: 07/02/2024

INDICATIONS

Xolair is indicated:

- **Moderate-to-severe persistent allergic asthma**
- **Nasal polyps in adult beneficiaries**
- **IgE-mediated food allergy**
- **Chronic idiopathic urticaria (CIU)**

CLINICAL CRITERIA

Moderate-to-severe persistent allergic asthma

- The beneficiary must be 12 years of age or older.
- The beneficiary has a positive skin test or in vitro reactivity to a perennial aeroallergen.
- The beneficiary must weigh between 30 kg (66 lbs) and 150 kg (330 lbs)
- The beneficiary has a serum total IgE level, measured before the start of treatment, of ≥ 30 IU/ml and ≤ 700 IU/ml
- The beneficiary has documented ongoing symptoms of moderate-to-severe asthma (see table below) with a minimum three-month trial of previous combination therapy, including medium- or high-dose inhaled corticosteroids PLUS another controller medication (e.g. long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline, etc.)

Components of severity for classifying asthma as MODERATE may include any of the following (not all inclusive):
• Daily symptoms • Nighttime awakenings > 1 time per week, but not nightly • SABA use for symptom control occurs daily • Some limitations to normal activities • Lung function (percent predicted FEV_1) > 60%, but < 80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Chronic Idiopathic Urticaria (CIU)

- The beneficiary must be 12 years of age or older

- The beneficiary has failed a three-month trial on previous therapy with at least two H1 antihistamine products (see table below); **OR**
- The beneficiary has had a three-month trial on previous therapy with at least one H1 antihistamine product (see table below) AND one of the following leukotriene antagonists:
  - Montelukast OR Zafirlukast

- The underlying cause of the beneficiary's condition is not considered to be any other allergic conditions or other forms of urticaria
- The beneficiary has a documented baseline score from an objective clinical evaluation tool (e.g. urticaria activity score [UAS7], Dermatology Life Quality Index [DLQI], or Chronic Urticaria Quality of Life Questionnaire [CU-Q2oL])

H1 Antihistamine Products (not all inclusive)
Brompheniramine
Carbinoxamine
Cetirizine
Chlorpheniramine
Clemastine
Cyproheptadine
Desloratadine
Dexchlorpheniramine
Diphenhydramine
Fexofenadine
Hydroxyzine
Levocetirizine
Loratadine
Triprolidine

IgE-mediated food allergy

- The beneficiary is 1 year of age or older.
- The drug is prescribed for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods.
  - **Note**: The drug is to be used in conjunction with food allergen avoidance.

Nasal Polyps

- The beneficiary is 18 years of age or older.
- The beneficiary has had an inadequate response to nasal corticosteroids as add-on maintenance treatment.

APPROVAL DURATION

Authorization is for 6 months and is eligible for renewal

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., symptoms of anaphylaxis, malignancy, symptoms similar to serum sickness, eosinophilic conditions, including vasculitic rash, worsening pulmonary symptoms, cardiac complications, or neuropathy, especially upon reduction of oral corticosteroids); **AND**

Moderate-to-severe persistent allergic asthma

- The beneficiary must weigh between 30 kg (66 lbs) and 150 kg (330 lbs)
- Treatment with Xolair (omalizumab) has resulted in clinical improvement, as documented by one or more of the following:
  - Decreased utilization of rescue medications
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
  - Improvement in lung function (increase in percent predicted FEV1 or PEF) from pretreatment baseline
  - Reduction in reported symptoms (e.g., decrease in asthma symptom score), as evidenced by decreases in frequency or magnitude of one or more of the following:
    - Asthma attacks
    - Chest tightness or heaviness
    - Coughing or clearing throat
    - Difficulty taking deep breath or difficulty breathing out
    - Shortness of breath
    - Sleep disturbance, night wakening, or symptoms upon awakening
    - Tiredness
    - Wheezing/heavy breathing/fighting for air

Chronic idiopathic urticaria (CIU)

- Treatment with Xolair (omalizumab) has resulted in clinical improvement, as documented by improvement from baseline using objective clinical evaluation tools, such as Urticaria Activity Score (UAS7), Dermatology Life Quality Index (DLQI), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL); **AND**
- Submitted current UAS7, DLQI, or CU-Q2oL was recorded within past 30 days

Table 1: ADMINISTRATION EVERY 4 WEEKS Xolair Doses (milligrams) Administered by Subcutaneous (SC) Injection Every 4 Weeks for Adults and Adolescents (12 Years of Age or Older) with Asthma				
Pre-treatment Serum IgE (IU/mL)	**Body Weight (kg)**			
	30-60	> 60-70	> 70-90	> 90-150
≥ 30-100	150	150	150	300
> 100-200	300	300	300	
> 200-300	300	*	*	*
> 300-400	*	*	*	*
> 400-500	*	*	*	*
> 500-600	*	*	*	*
*** See Table 2**				

Table 2: ADMINISTRATION EVERY 2 WEEKS Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 Weeks for Adults and Adolescents (12 Years of Age or Older) with Asthma				
Pre-treatment Serum IgE (IU/mL)	**Body Weight (kg)**			
	30-60	> 60-70	> 70-90	> 90-150
≥ 30-100	*	*	*	*
> 100-200	*	*	*	225
> 200-300	*	225	225	300
> 300-400	225	225	300	‡
> 400-500	300	300	375	‡
> 500-600	300	375	‡	‡
> 600-700	375	‡		
*** See Table 1** **‡ DO NOT DOSE**				

BILLING/CODING INFORMATION

Applicable service codes:

- J2357 – Injection, omalizumab, 5 mg: 1 billable unit = 5 mg

YCANTH (CANTHARIDIN)

Updated: 01/19/2024

INDICATIONS

Molluscum contagiosum

CLINICAL CRITERIA

- The beneficiary is 2 years of age or older.
- Ycanth is prescribed and administered by a dermatologist or healthcare provider experienced in treating dermatological conditions.
- The beneficiary has documentation of Ycanth use for the topical treatment of molluscum contagiosum.
- The beneficiary has documentation of persistent itching or pain.
- The beneficiary has documentation of trial and failure of at least one of the following in the last 90 days:
  - Salicylic acid
  - Topical retinoids (e.g., adapalene, tretinoin)
  - Imiquimod 5% cream
  - Cryotherapy
  - Pulsed dye laser

APPROVAL DURATION

Approval duration is 3 months (4 treatment doses).

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Documentation that the beneficiary has continued presence of molluscum lesions.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- C9164 – Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)

YERVOY (IPILIMUMAB)

Updated: 04/22/2025

INDICATIONS

Yervoy is indicated for:

- **Melanoma**
  - The drug is used as a single agent or in combination with nivolumab (Opdivo) for treatment of unresectable or metastatic melanoma in adult and pediatric beneficiaries 12 years of age or older.
  - The drug is used for adjuvant treatment of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm in adult beneficiaries who have undergone complete resection, including total lymphadenectomy.
- **Renal cell carcinoma**
  - The drug is used in combination with nivolumab (Opdivo) for treatment of adult beneficiaries with intermediate or poor risk, previously untreated advanced renal cell carcinoma.
- **Colorectal cancer**
  - The drug is used in combination with nivolumab (Opdivo) for treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient dMMR metastatic colorectal cancer (CRC) in adult and pediatric beneficiaries 12 years of age or older.
- **Hepatocellular carcinoma**
  - The drug is used in combination with nivolumab (Opdivo) for first-line treatment of adults with unresectable or metastatic HCC.
- **Non-small cell lung cancer (NSCLC)**
  - The drug is used as first-line treatment in combination with nivolumab (Opdivo) for adult beneficiaries with metastatic non-small cell lung cancer expressing PD-L1(≥ 1%) as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
  - The drug is used as first-line treatment in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy for adult beneficiaries with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- **Malignant pleural mesothelioma**
  - The drug is used as first-line treatment in combination with nivolumab (Opdivo) for adult beneficiaries with unresectable malignant pleural mesothelioma.
- **Esophageal cancer**
  - The drug is used as first line treatment in combination with nivolumab (Opdivo) for treatment of adult beneficiaries with unresectable advanced or metastatic esophageal squamous cell carcinoma.

APPROVAL DURATION

Approval is for 6 months and may be renewed for up to 2 years of therapy.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., immune-mediated reactions, such as enterocolitis, hepatitis, neuropathies, endocrinopathies, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9228 – Injection, ipilimumab, 1 mg: 1 billable unit = 1 mg

YESCARTA (AXICABTAGEN CILOLEUCEL)

Updated: 10/17/2024

INDICATIONS

Yescarta is indicated for treatment of:

- Adult beneficiaries with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult beneficiaries with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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.

RECOMMENDED INDICATIONS AND USAGE

- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary does not have a clinically significant active systemic infection or inflammatory disorder.
- The beneficiary has been 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)
- The beneficiary does not have primary central nervous system lymphoma.
- The beneficiary did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT).

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older
- The beneficiary has large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- The beneficiary has not received prior CAR-T therapy.

APPROVAL DURATION

Approval is for one treatment course (1 dose of Yescarta) and may not be renewed.

RENEWAL/REAUTHORIZATION

May NOT be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9999 – Not otherwise classified, antineoplastic drugs
- Q2041 – Axicabtagene ciloleucel, up to 200 million autologous Anti-CD19 CAR T cells, including Leukapheresis and dose preparation procedures, per infusion

YONDELIS (TRABECTEDIN)

Updated: 07/03/2024

INDICATIONS

Yondelis is indicated for treatment of:

- **Liposarcoma or leiomyosarcoma**

CLINICAL CRITERIA

- **Liposarcoma or leiomyosarcoma**
  - The beneficiary has unresectable or metastatic liposarcoma or leiomyosarcoma.
  - The drug is used as subsequent therapy after an anthracycline-containing regimen (e.g., doxorubicin, etc.)
  - Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be monitored regularly for need to modify the dose or discontinue the drug permanently.

COMPENDIA RECOMMENDED INDICATIONS

- **Liposarcoma or leiomyosarcoma**
  - Doxorubicin plus Yondelis (trabectedin) is used as first-line therapy in beneficiaries with metastatic or unresectable leiomyosarcomas.
- **Soft tissue sarcoma (including synovial sarcoma)**
  - The drug is used as second-line therapy.
- **Uterine sarcoma**
  - The beneficiary has uterine leiomyosarcoma.
  - The drug is used as subsequent therapy after an anthracycline-containing regimen (e.g., doxorubicin, etc.)
  - The beneficiary has unresectable, metastatic, or recurrent disease; **OR**
  - The beneficiary has disease that is not suitable for primary surgery
- **Note**: Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and assessed at regular intervals as needed during treatment for Compendia indications as well.

APPROVAL DURATION

Approval is for 6 months and may be renewed

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., cardiomyopathy, rhabdomyolysis, hepatotoxicity or severe hepatic impairment, capillary leak syndrome, severe neutropenia, extravasation resulting in tissue necrosis, etc.)

- Left ventricular ejection fraction (LVEF) has not had an absolute decrease of ≥ 15% from baseline OR is not below the lower limit of normal with an absolute decrease of ≥ 5% (LVEF results must be within the previous 3 months).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9352 – Injection, trabectedin, 0.1 mg; 1 billable unit = 0.1 mg

YUTIQ (FLUOCINOLONE ACETONIDE IMPLANT)

Updated: 10/17/2024

INDICATIONS

Yutiq is indicated for treatment of:

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

CLINICAL CRITERIA

- The beneficiary is 12 years of age or older.
- The beneficiary is free of ocular or periocular infections.
- The beneficiary has had chronic disease for at least one year.
- Other causes of disease have been ruled out (e.g., infection, malignancy, etc.)

APPROVAL DURATION

Approval is for 1 implant per eye every 36 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Absence of unacceptable toxicity from the drug (e.g., cataract formation, endophthalmitis, increased intra-ocular pressure, etc.)
- Disease is responsive to therapy, as indicated by:
  - Stabilization of visual acuity or improvement in Best Corrected Visual Acuity (BCVA) score when compared to baseline; **OR**
  - Improvement in vitreous haze score (decrease in inflammation)

BILLING/CODING INFORMATION

Applicable Procedure Codes

J7314 − Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg; 1 billable unit = 0.01 mg

ZALTRAP (ZIV-AFLIBERCEPT)

Updated: 11/13/2025

INDICATIONS

Zaltrap is indicated for the treatment of beneficiaries with:

- **Colon and rectal cancer**

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The beneficiary has diagnosis of advanced metastatic disease.
- The beneficiary has previously been treated with an oxaliplatin-containing regimen (e.g., FOLFOX, CapeOX).
  - **Note**: FOLFOX includes 5-fluorouracil (5-FU), leucovorin, and oxaliplatin. CapeOX includes capecitabine and oxaliplatin.
- Zaltrap is prescribed by or in consultation with an oncologist.
- Zaltrap is used in combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan)
  - **Note**: NCCN guidelines suggest that use of Zaltrap (ziv-aflibercept) should be reserved for beneficiaries with a contraindication or intolerance to bevacizumab (preferred) product.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has documentation of disease response with treatment and does not show evidence of progressive disease while on therapy.
- Absence of unacceptable toxicity from the drug, (e.g., hemorrhage, gastrointestinal perforation, fistula formation, hypertensive crisis, hypertensive encephalopathy, neutropenia, etc.).

RECOMMENDED DOSING

4 mg/kg administered by intravenous infusion no more frequently than once every 2 weeks.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9400 – Injection, ziv-aflibercept, 1 mg; 1 billable unit = 1 mg

ZEPZELCA (LURBINECTEDIN)

Updated: 10/07/2025

INDICATIONS

Zepzelca is indicated for treatment of:

- **Small cell lung cancer (SCLC)**

CLINICAL CRITERIA

- The beneficiary is 18 years of age or older.
- The drug is used as single therapy.

Small cell lung cancer

- The beneficiary has metastatic disease.
- The drug is used as subsequent therapy for disease progression on or after platinum-based chemotherapy (i.e., cisplatin, carboplatin).
- The drug is used in combination with atezolizumab (Tecentriq) or atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza) for the maintenance treatment of ES-SCLC in adult beneficiaries whose disease has not progressed after first-line induction therapy with:
  - Tecentriq Hybreza or intravenous atezolizumab; **AND**
  - Carboplatin plus etoposide.

APPROVAL DURATION

Adjuvant treatment is approved until disease progression (using accepted tumor evaluation criteria) or unacceptable toxicity from the drug.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.
- Absence of unacceptable toxicity from the drug (e.g., myelosuppression, hepatotoxicity, etc.)

BILLING/CODING INFORMATION

- J9223 – Injection, lurbinectedin, 0.1 mg; 1 billable unit = 0.1 mg.
- Zepzelca 4 mg single dose vial for injection

ZILRETTA (TRIAMCINOLONE ACETONIDE ER)

Updated: 10/17/2024

INDICATIONS

Zilretta is indicated as an intra-articular injection for the management of:

- **Osteoarthritis pain of the knee**

CLINICAL CRITERIA

- The beneficiary has a radiographically confirmed diagnosis of osteoarthritis of the knee
- The beneficiary has had a trial and failure of BOTH of the following conservative methods, which have not resulted in functional improvement after at least three 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.])
  - Pharmacologic approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.)
- The beneficiary reports pain that interferes with functional activities (e.g., ambulation, prolonged standing)
- The beneficiary does not have any conditions that would preclude intra-articular injections (e.g., active joint infection, unstable joint, etc.)

APPROVAL DURATION

Approval is for one dose per knee and may NOT be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3304 – Injection, triamcinolone acetonide, extended release, microsphere formulation, 1 mg; 1 billable unit = 1 mg

ZINPLAVA (BEZLOTOXUMAB)

Updated: 10/17/2024

INDICATIONS

Zinplava is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in adult and pediatric beneficiaries 1 year of age or older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.

- ***Clostridium difficile* infection (CDI)**

CLINICAL CRITERIA

- The beneficiary is 1 year of age or older.
- The beneficiary must have a confirmed diagnosis of CDI:
  - Diarrhea (passage of 3 or more loose bowel movements in 24 or fewer hours) (DOCUMENTATION IS REQUIRED)
  - Positive stool test for toxigenic *C. difficile* from stool sample collected no more than 7 days prior to scheduled infusion (DOCUMENTATION IS REQUIRED)
- The beneficiary is receiving antibacterial therapy for *Clostridium difficile* infection
- The beneficiary is at high risk of CDI recurrence, having any one of the following:
  - The beneficiary is 65 years of age or older and has a history of 2 or more prior episodes of CDI within the previous 6 months
  - Immunocompromised state
  - C. difficile ribotype 027
  - Clinically severe CDI (meeting any one of the definitions below)
    - **The College of Gastroenterology (ACG, 2013):**
      - Albumin < 3 g/dL plus one of the following:
        - White blood cell (WBC) ≥ 15,000 cells/mm^3; **OR**
        - Abdominal tenderness
    - **The Infectious Disease Society of America (IDSA):**
      - WBC ≥ 15,000 cells/ mm^3 and serum creatinine level > 1.5 x baseline creatinine level
    - **ZAR (2007) score ≥ 2:**
      - The beneficiary is > 60 years of age (1 point)
      - Body temperature > 38.3°C (> 100°F) (1 point)
      - Albumin level 2.5 mg/dL (1 point)
      - Peripheral white blood cell count > 15,000 cells/mm^3 within 48 hours (1 point)
      - Endoscopic evidence of pseudomembranous colitis (2 points)
      - Treatment in intensive care unit (2 points)

EXCLUSIONS

- Zinplava (bezlotoxumab) is not indicated for the treatment of *Clostridium difficile* infection (CDI). The use of Zinplava (bezlotoxumab) is considered investigational when the above indications are not met, as well as for all other conditions, including first-line therapy.

- Zinplava should be used only in conjunction with antibacterial drug treatment of CDI.

APPROVAL DURATION

Authorization is for a one-time approval of one Zinplava dose (repeat doses have not been studied and are considered investigational).

RENEWAL/REAUTHORIZATION

May NOT be renewed

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J0565 – Injection, bezlotoxumab, 10 mg

ZOLGENSMA (ONASEMNOGENE ABEPARVOVEC-XIOI)

Updated: 10/17/2024

INDICATIONS

Zolgensma is indicated for treatment of:

- **Spinal muscular atrophy (SMA)** in pediatric beneficiaries less than 2 years of age

CLINICAL CRITERIA

- The beneficiary has documentation of a diagnosis of SMA with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene
- The beneficiary is less than 2 years of age.
- The beneficiary has documentation of a test confirming anti-adeno-associated virus serotype 9 (AAV9) antibody titer ≤ 1:50
- The prescribing physician must be a neurologist/pediatric neurologist who has experience in the diagnosis and treatment of SMA.
- The beneficiary has baseline documentation of motor function skills test

EXCLUSIONS

- Repeat administrations (Zolgensma is a one-time, single-dose intravenous therapy)
- Beneficiaries with advanced SMA
  - Complete limb paralysis
- Permanent ventilation, defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.
- Concomitant use of Zolgensma and Spinraza is considered investigational.
- Concomitant use of Zolgensma and risdiplam (Evrysdi) is considered investigational.

APPROVAL DURATION

Zolgensma is a one-time, single-dose intravenous infusion.

RENEWAL/REAUTHORIZATION

Zolgensma may not be renewed.

BILLING/CODING INFORMATION

Applicable Procedure Codes

- Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5 x 10^{15} vector genomes

ZYNLONTA (LONCASTUXIMAB TESIRINE-LPYL)

Updated: 10/17/2024

INDICATIONS

Zynlonta is indicated for treatment of:

- **B-cell Lymphoma, including large diffuse B-cell lymphoma (DLBCL)**

CLINICAL CRITERIA

- The beneficiary is at least 18 years of age.
- The drug is prescribed by or in consultation with a hematologist/oncologist.
- The beneficiary has a diagnosis of one of the following:
  - Diffuse large B-cell lymphoma (DLBCL)
  - DLBCL arising from low-grade lymphoma.
  - High-grade B-cell lymphoma
- The disease is relapsed or refractory.
- The beneficiary has received at least two prior systemic therapies (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine, etc.)

APPROVAL DURATION

Approval is for 6 months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary does not show evidence of progressive disease while on therapy.
- Absence of unacceptable toxicity from the drug (e.g., severe effusion/edema, myelosuppression, infections, severe cutaneous reactions, etc.)

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J3590 – Injection, loncastuximab tesirine-lpyl, 0.075 mg
- J9359 – Injection, loncastuximab tesirine-lpyl, 0.075 mg

ZYNYZ (RETIFANLIMAB-DLWR)

Updated: 10/31/2025

INDICATIONS

Zynyz is indicated for the treatment of:

- **Squamous cell carcinoma of the anal canal (SCAC)**
- **Merkel cell carcinoma (MCC)**

CLINICAL CRITERIA

Anal carcinoma

- The beneficiary has a diagnosis of locally recurrent, progressive, or metastatic squamous cell anal carcinoma (SCAC).
- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy.
- The drug may be prescribed as one of the following:
  - A single agent for locally recurrent disease with progression on or intolerance to platinum-based chemotherapy; **OR**
  - Subsequent therapy for metastatic disease; **OR**
  - In combination with carboplatin and paclitaxel for treatment of inoperable locally recurrent disease

Merkle cell carcinoma

- The beneficiary has a diagnosis of Merkel cell carcinoma (MCC).
- The drug is prescribed by or in consultation with an oncologist.
- The beneficiary has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy.
- The drug may be used as monotherapy for metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in beneficiaries who are not candidates for surgery or radiation therapy.

APPROVAL DURATION

Approval is for six months and may be renewed.

RENEWAL/REAUTHORIZATION

Authorizations can be renewed based on the following:

- The beneficiary has documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression.
- Absence of unacceptable toxicity from the drug (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.).

BILLING/CODING INFORMATION

Applicable Procedure Codes

- J9345 – Injection, retifanlimab-dlwr, 1 mg; 1 billable unit = 1 mg

REVISION HISTORY

Date	Issues/Updates
01/01/2026	Document creation with style and formatting overhaul