Injections: Drugs S-Z Policy

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This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Injections: Drugs A-D Policy*
- *Injections: Drugs E-H Policy*
- *Injections: Drugs I-M Policy*
- *Injections: Drugs N-R Policy*
- *Injections: Hydration*
- *Immunizations*

‹‹Sargramostim (LEUKINE®)››

Sargramostim is a recombinant human granulocyte-macrophage colony stimulating factor (rhu GM-CSF) produced by recombinant DNA technology in a yeast expression system. GM-CSF is a hematopoietic growth factor which induces partially committed progenitor cells to divide and differentiate in the granulocyte-macrophage pathways including neutrophils, monocytes/macrophages and myeloid-derived dendritic cells.

Indications

‹‹All FDA approved indications.

Dosage

FDA approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.››

Billing

HCPCS code J2820 (injection, sargramostim [GM-CSF], 50 mcg).

‹‹Suggested ICD-10 Diagnosis Codes››

D70.1
‹‹T66››
Z51.11
Z51.89
‹‹Z52.001››
Z94.81
Z94.84

‹‹Sebelipase Alfa (Kanuma®)

Sebelipase alfa is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme that binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebelipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol, and free fatty acids.

Indications

All FDA-approved indications.

Dosage

FDA-approved indications dosages.

TAR Requirements

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Required ICD-10-CM Diagnosis Code

E75.5››

Billing

HCPCS code J2840 (injection, sebelipase alfa, 1 mg)

Secretin

Secretin is indicated for use in secretin stimulation testing to:

- Aid in the diagnosis of pancreatic exocrine dysfunction
- Aid in the diagnosis of gastrinoma
- Facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography.

Dosage

The maximum allowable dosage is 48 mcg.

Billing

HCPCS code J2850 (injection, secretin, synthetic, human, 1 mcg).

Siltuximab

Siltuximab is a human-mouse chimeric monoclonal antibody that binds human interleukin-6 (IL-6) and prevents the binding of IL-6 to both soluble and membrane-bound IL-6 receptors. IL-6 has been shown to be involved in diverse normal physiologic processes such as induction of immunoglobulin secretion. Over production of IL-6 has been linked to systemic manifestations in patients with multicentric Castleman’s disease (MCD).

Indications

For the treatment of patients 18 years of age or older with MCD who are human immunodeficiency virus negative and human herpesvirus-8 negative.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Dosage

The recommended dose is 11mg/kg intravenously every three weeks until treatment failure.

Billing

HCPCS code J2860 (injection, siltuximab, 10 mg).

Sodium Ferric Gluconate Complex in Sucrose

Sodium ferric gluconate complex in sucrose, 12.5 mg injection (HCPCS code J2916) is reimbursable when used to treat patients with iron deficiency anemia and for patients undergoing long term hemodialysis and who are also receiving supplemental erythropoietin (EPO) therapy. Sodium ferric gluconate complex may be used as an alternative to oral iron therapy.

Dosage

The recommended dosage is 10 ml (125 mg of elemental iron) administered intravenously during the dialysis session. Patients may continue to require therapy with sodium ferric gluconate complex in sucrose at the lowest dose necessary to maintain target levels of hemoglobin.

The maximum dosage is 125 mg per day.

Somatropin for HIV-Associated Wasting

Somatropin is used for the treatment of HIV-associated wasting and is reimbursable only with an approved TAR. A TAR will be granted in four-week intervals to a maximum of 12 continuous weeks of therapy. Treatment must be reevaluated after four weeks and eight weeks of therapy.

Initial Therapy: Criteria

Criteria for the initial 28 days of treatment of HIV-associated wasting with somatropin:

- Documentation in the medical record of complete history and physical examination including:
  - History of nutritional status including appetite, estimation of caloric intake, gastrointestinal function including presence of diarrhea and number of daily stools, and history of endoscopic procedures
  - Psychosocial evaluation, including presence of significant anxiety and/or depression affecting food intake
- Record of the following measurements:
  - Height, weight, ideal body weight, body mass index (BMI)
  - Body cell mass (BCM) by bioelectrical impedance analysis (BIA)
  - Serial measurements – weekly
- Patients must meet one of the following criteria for HIV-associated wasting:
  - 5 percent BCM loss within the preceding six months
  - In men: BCM less than 35 percent of total body weight and BMI less than 27 kg/m^2
  - In women: BCM less than 23 percent of total body weight and BMI less than 27 kg/m^2
  - BMI less than 20 kg/m^2
  - BMI greater than 20 kg/m^2 and less than 25 kg/m^2 and
    - ❖ 10 percent unintentional weight loss within the preceding 12 months or
    - ❖ 7.5 percent unintentional weight loss within the preceding six months

- Patients should have an evaluation of gastrointestinal function with attention to the presence of malabsorption, a review of food intake, amount of daily calories and estimate of physical activity level.
- An active malignancy other than Kaposi's sarcoma has been excluded clinically, through diagnostic laboratory examination, and/or radiographically.
- Male patients should have a serum testosterone level and, if low, a trial of testosterone replacement therapy.
- Patients must have a viral load assay and a CD4 count and must be undergoing treatment with an appropriate antiretroviral therapy regimen.
- Patients should have a trial with an appetite stimulant if they have inadequate caloric intake and anorexia.
- For male patients, an initial trial of androgen is recommended for HIV-associated wasting. If this is omitted, a statement should be provided documenting the clinical decision to proceed directly with somatropin therapy.
- Patients must receive somatropin within recommended dosing guidelines for body weight.

Reassessment of Therapy Through 12 Weeks: Criteria

Criteria for reassessment of therapy through 12 weeks:

- Treatment must be re-evaluated after four weeks and eight weeks of therapy. Repeat weight assessment and documentation is required at four weeks and eight weeks of therapy to assure weight stabilization.
- Therapy must be discontinued in patients who continue to lose weight in the first four weeks of treatment.
- If, after four weeks of therapy, weight loss has stopped or if the patient is gaining weight, somatropin may be continued for another 28 days.
- If, after eight weeks of therapy, the patient is losing or has failed to gain weight from the original measurement, somatropin must be stopped.
- If the patient had initially gained weight at four weeks, but has neither gained nor lost weight at the eight-week re-evaluation, somatropin may be continued for another 28 days.

- A maximum of 12 weeks of treatment is allowed with authorization. Claims without authorization will be denied.

Note: Authorization is limited to four-week intervals.

Continued Therapy Beyond 12 Weeks: Criteria

Criteria for continued therapy beyond the initial 12 weeks:

- All patients must stop somatropin following the initial 12-week treatment for an eight-week period of observation unless there is documentation that HIV-associated wasting is still present. During the eight-week observation period, body weight, BMI and BCM should be monitored on a weekly basis.
- Therapy beyond 12 weeks may be continued with a patient who has demonstrated a beneficial response to somatropin during the initial 12 weeks of therapy (defined as a two percent or greater increase in body weight or BCM) and
  - Still exhibits evidence of wasting (BMI less than 20 kg/m^2) or
  - Has a BCM not yet normalized (BCM less than 40 percent in non-obese men or less than 28 percent in non-obese women).
- As long as the patient continues to gain weight or BCM, somatropin may be extended every 28 days, with authorization, until BCM and/or weight are normalized.
- Once BCM and/or weight have normalized, somatropin should be stopped.

Reinitiating Somatropin Therapy Within Six Months: Criteria

Criteria for reinitiating somatropin therapy within six months:

- Patients may resume somatropin therapy within six months of initial therapy if there is documentation of an unintentional five percent loss of body weight or BCM loss of greater than five percent or any of the criteria for HIV-associated wasting within six months after completion of an uninterrupted 12-week course of somatropin therapy.
- Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four and eight week intervals during the second 12-week course of therapy. A recent copy of the patient's BIA documenting the BCM loss is required with TAR submission.

Repeat Somatropin Therapy After Cessation: Criteria

Criteria for repeat somatropin therapy six months after cessation of treatment:

- If the patient has not re-initiated somatropin six months after completing an uninterrupted 12-week course of therapy, somatropin may be repeated, provided the criteria for initial 28 days of therapy are met. Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four- and eight-week intervals during the second 12-week course of therapy. A recent copy of the patient's BIA is required with TAR submission.
- Trials of alternate treatment may be omitted if previous use in the patient was unsuccessful. The use of somatropin beyond the initial 12-week course must meet the criteria stated above for continued treatment.

Sotalol

Sotalol has both beta-adrenoreceptor blocking (Vaughan Williams Class II) and cardiac action potential duration prolongation (Vaughan Williams Class III) antiarrhythmic properties. Intravenous sotalol hydrochloride is a racemic mixture of d- and l-sotalol. Both isomers have similar Class III antiarrhythmic effects, while the l-isomer is responsible for virtually all of the beta-blocking activity.

Indications

Sotalol is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AFIB/AFL]) in patients with symptomatic AFIB/AFL who are currently in sinus rhythm. Because sotalol can cause life-threatening ventricular arrhythmias, it should be reserved for patients in whom AFIB/AFL is highly symptomatic. Sotalol is indicated for patients 18 years of age and older.

Authorization

A *Treatment Authorization Request* (TAR) is required for reimbursement.

Required Codes

Sotalol is reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes:

I48.0 thru I48.4

I48.91

I48.92

Dosage

Starting adult dose is 75 mg administered twice daily. If creatinine clearance is between 60 and 40 mL/min, administer once daily, if less than 40 mg/mL, sotalol is not recommended.

Billing

HCPCS code C9482 (injection, sotalol hydrochloride, 1 mg)

‹‹Spesolimab-sbzo (Spevigo®)

Spesolimab-sbzo is a humanized monoclonal immunoglobulin G1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. Binding of spesolimab-sbzo to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL-36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. The precise mechanism linking reduced IL36R activity and the treatment of flares of GPP is unclear.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

Treatment Authorization Request (TAR) is required for reimbursement››

‹‹TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for all FDA-approved indications and dosages
- Patient must have a diagnosis of generalized pustular psoriasis (GPP) flares
- Must be prescribed by or in consultation with a dermatologist
- Patient must be 18 years of age or older
- Patient has no current active infections
- Patient is not currently on retinoids/methotrexate/cyclosporine prior to initiation of spevigo
- Documentation of a negative tuberculosis (TB) infection prior to initiating treatment or pretreatment with antituberculosis therapy in patients with latent TB
- Patient does not have an immediate life-threatening flare of GPP or requiring intensive care treatment
- Patient does not have SAPHO syndrome (inflammatory bone disorders that may be associated with skin changes)

Approval is for 3 months (maximum of 2 doses 1 week apart).

Billing

HCPCS code: J1747, (Injection, spesolimab-sbzo, 1 mg)

Required ICD-10-CM Diagnosis Codes

L40.1

Prescribing Restriction(s)

Maximum dose: 900 mg/900 units

Frequency of billing: 900 mg/900 units every week for up to 2 doses

Note: Spevigo is available through the following specialty distributor:
Accredo Specialty Pharmacy
1-800-803-2523››

Sutimlimab-jome (Enjaymo™)

Sutimlimab-jome is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway (CP) and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Sutimlimabjome does not inhibit the lectin and alternative pathways. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of RBCs, resulting in inhibition of hemolysis in patients with cold agglutinin disease (CAD).

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Enjaymo is considered medically necessary when all of the following criteria are met:

- Must be used for FDA approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with a hematologist, immunologist or oncologist
- Patient has a diagnosis of primary cold agglutinin disease (CAD) as defined by all of the following:
  - Evidence of hemolysis (e.g., high reticulocyte count, high LDH, high indirect bilirubin, low haptoglobin)
  - Positive direct antiglobulin (Coombs) test for C3d only (or, in a minority, C3d plus weak IgG)
  - Cold agglutinin titer of equal to or greater than 64 at 4°C
- Patient has had at least one blood transfusion in the previous six months
- Patient has chronic hemolysis with a hemoglobin (Hgb) level of less than10g/dL
- Patient has symptomatic anemia or cold-induced ischemic symptoms interfering with daily living (for example, fatigue, dyspnea, acrocyanosis, Reynaud's phenomenon, pain or discomfort in swallowing cold food or liquids, etc.
- Patients has received vaccinations against Neisseria meningitidis, Haemophilus influenzae, and Streptococcus pneumoniae at least two weeks before initiating sutimlimab; if therapy is started urgently, vaccines should be provided as soon as possible
- Patient does not have cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy

Initial approval is for six months

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has experienced clinical benefit as evidenced by at least one of the following:
  - Patient did not receive a blood transfusion or achieved transfusion independence
    - Patient's hemoglobin (Hgb) level became equal to or greater than 12 g/dL or Hgb level increased by equal to or greater than 2 g/dL from baseline
  - Patient had a decrease in mean bilirubin and LDH values compared to baseline

Reauthorization is for 12 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code: J1302, (injection, sutimlimab-jome, 10 mg)

Required ICD-10 Diagnosis Codes

D59.12

Prescribing Restriction(s)

Frequency of billing equals 7,500 mg/750 units weekly for two weeks then every two weeks

Maximum billing unit(s) equals 7,500 mg/750 units

Taliglucerase Alfa

Taliglucerase alfa, a hydrolytic lysosomal glucocerebroside-specific enzyme for intravenous infusion, is a recombinant active form of the lysosomal enzyme, β-glucocerebrosidase, which is expressed in genetically modified carrot plant root cells cultured in a disposable bioreactor system. B-glucocerebrosidase is a lysosomal glycoprotein enzyme that catalyzes the hydrolysis of the glycolipid glucocerebroside to glucose and ceramide.

Indications

For use for adults with confirmed diagnosis of Type 1 Gaucher disease.

Authorization

The *Treatment Authorization Request* (TAR) must include a diagnosis of Type 1 Gaucher disease. For other TAR requirements, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E-H Policy* section in this manual.

Dosage

The recommended dose is 60 units/kg of body weight administered once every two weeks as a 60 thru 120 minute intravenous infusion. The maximum dose is 8,160 mg per day.

Billing

HCPCS code J3060 (injection, taliglucerase alfa, 10 units).

Tbo-Filgrastim

Tbo-filgrastim is a non-glycosylated recombinant methionyl human granulocyte colony-stimulating growth factor (r-metHuG-CSF) manufactured by recombinant DNA technology using the bacterium strain E. coli K802. It binds to G-CSF receptors and stimulates proliferation neutrophils. G-CSF is known to stimulate differentiation commitment and some end-cell functional activation, which increases neutrophil counts and activity.

Indications

To reduce the duration of severe neutropenia in adult patients (18 years of age and older) with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Dosage

The recommended dose of tbo-filgrastim is 5 mcg/kg per day administered as a subcutaneous injection. Administer the first dose of tbo-filgrastim no earlier than 24 hours following myelosuppressive chemotherapy.

Required Codes

Tbo-filgrastim is reimbursable when billed with one of the following ICD-10-CM diagnosis codes:

D70.1	Z51.11
D70.2	Z51.89

Billing

HCPCS code J1447 (injection, tbo-filgrastim, 1 microgram).

Tedizolid Phosphate

Tedizolid phosphate, 1 mg injection (HCPCS code J3090) is restricted to patients 18 years of age and older.

Teplizumab-mzwv (TZIELD™)

Teplizumab-mzwv binds to CD3 (a cell surface antigen present on T lymphocytes) resulting in a partial agonistic signaling and deactivation of pancreatic beta cell autoreactive lymphocytes. Teplizumab-mzwv leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

‹‹Must submit clinical documentation to substantiate the following:››

- Must be used for FDA-approved indications and dosages
- Patient must be 8 years of age or older
- Must be prescribed by or in consultation with an endocrinologist
- ‹‹Patient has a diagnosis of Stage 2 type 1 diabetes (TID) confirmed by at least two positive pancreatic islet cell autoantibodies:››
  - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Insulin autoantibodies (IAA)
  - Insulinoma-associated antigen 2 autoantibodies (IA-2A)
  - Zinc transporter 8 autoantibodies (ZnT8A)
  - Islet-cell autoantibodies (ICA)

- ‹‹Patient has dysglycemia (abnormal blood glucose) without overt hyperglycemia defined using an oral glucose tolerance test (OGTT) OR alternative method if appropriate and OGTT is not available:››
  - According to the American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes, dysglycemia may be diagnosed based on any of the following:
    - ❖ 2-hour plasma glucose (PG) level of 140 to 199 mg/dL (7.8 to 11.0 mmol/L) during OGTT
    - ❖ A fasting plasma glucose (FPG) level of 100 to 125 mg/dL (5.6 to 6.9 mmol/L)
- Patient does not have any of the following:
  - Stage 3 type 1 diabetes
  - Clinical history consistent with type 2 diabetes
  - An active serious infection or chronic infection, including but not limited to Epstein-Barr virus or cytomegalovirus.
  - Serological evidence of past current or past HIV, hepatitis B, or hepatitis C infection
  - Prior treatment with other monoclonal antibody in past one year
- CBC and liver chemistries do not show any of the following lab abnormalities
  - Lymphocyte count less than 1,000 lymphocytes/mcL
  - Hemoglobin less than 10 g/dL
  - Platelet count less than 150,000 platelets/mcL
  - Absolute neutrophil count less than 1,500 neutrophils/mcL
  - Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN

Initial authorization is for 3 months (14-day treatment course).

Reauthorization is not approvable.

Age Limits

Must be 8 years of age or older.

Billing

‹‹HCPCS code J9381 (injection, teplizumab-mzwv, 5 mcg)››

Required ICD-10-CM Diagnosis Codes

E10.8, E10.9

‹‹Prescribing Restrictions

Frequency of billing is one treatment in a lifetime.››

Teprotumumab-trbw (Tepezza)

Teprotumumab's mechanism of action in patients with thyroid eye disease has not been fully characterized. Teprotumumab binds to insulin-like growth factor-1 receptor inhibitor and blocks its activation and signaling.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Teprotumumab-trbw will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a clinical diagnosis of Grave’s disease associated with active thyroid eye disease (TED) with a clinical activity score (CAS) of greater than or equal to 4 for the most severely affected eye or patient has moderately to severely active TED, associated with at least one of the following:
  - Lid retraction equal to or greater than 2 mm
  - Moderate or severe soft tissue involvement
  - Proptosis equal to or greater than 3 mm
  - Diplopia
  - Corneal exposure

- Patient must be euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine and free triiodothyronine levels less than 50 percent above or below the normal limits
- Must be prescribed by or in consultation with an ophthalmologist, endocrinologist or a physician who specializes in treatment of thyroid eye disease
- Patient does not require surgical ophthalmological intervention
- Patient must not have poorly controlled diabetes
- Diabetic patient must have well controlled disease (defined as HgbA1c less than 9.0 percent at most recent clinic visit)
- Patient has a contraindication, intolerance, or lack of response to glucocorticoids or a documented justification why the use of glucocorticoids is not appropriate

Authorization is for 12 months (a maximum of 8 infusions).

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J3241 (Injection, teprotumumab-trbw, 10 mg)

Suggested ICD-10-CM Diagnosis Codes

E05.00

Prescribing Restrictions

Frequency of billing equal to 10 mg/kg initial dose, then 20 mg/kg every 3 weeks for 7 additional doses

Tezepelumab-ekko (Tezspire™)

Tezepelumab-ekko is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2λ that binds to human TSLP with a dissociation constant of 15.8 pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade.

Airway inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes, ILC2 cells) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in airway inflammation. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of tezepelumab-ekko action in asthma has not been definitively established.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA- approved indications and dosages
- Patient must be 12 years of age or older
- Patient has a physician-diagnosed asthma for at least 12 months
- Must be prescribed by or in consultation with a pulmonologist, allergist or immunologist
- Patient is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS)

- Patient has persistent uncontrolled asthma as defined by at least one of the following:
  - An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline.
  - A history of at least 2 asthma exacerbation events within prior 12 months.
  - A history of at least 1 severe asthma exacerbation resulting in hospitalization within prior 12 months.
  - Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90% in adolescents] despite regular treatment with high dose inhaled corticosteroid (ICS) or with medium or high dose ICS plus a LABA with or without oral corticosteroids (OCS) and additional asthma controller medications such as leukotriene receptor inhibitors, long-acting anti-muscarinics (LAMA), or sustained-release theophylline.
- Patient will not use tezepelumab-ekko as monotherapy

Initial approval is for 12 months

Continued therapy:

Patient has experienced improvement in asthma control as evidenced by at least one of the following:

- Reductions in Annual Asthma Exacerbation Rate as shown by any of the following:
  - Improvement in patient's Forced Expiratory Volume in 1 Second (FEV1), peak expiratory flow, nighttime awakenings, or any other symptoms that would require an increase in OCS dose
  - Reduction in ED visits requiring use of oral/systemic corticosteroids and/or hospitalization
  - Reduction in use of short-acting bronchodilator rescue medications
- Improvement from baseline in Asthma Control Questionnaire-6(ACQ-6) or Asthma Control Test (ACT) score

Reauthorization is for 12 months

Age Limits

Must be 12 years of age or older

Billing

HCPCS code: J2356, (injection, tezepelumab-ekko, 1 mg)

Required ICD-10 Diagnosis Codes

J45.50, J45.51.

Prescribing Restriction(s)

Frequency of billing equals 210 mg/210 units every four weeks

Maximum billing unit(s) equals 210 mg/210 units

Thyrotropin Alfa

Thyrotropin alfa is reimbursable for use in the following groups: (1) as a diagnostic tool for serum thyroglobulin testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer and (2) as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

Dosage

A two-injection regimen is recommended. The two-injection regimen is thyrotropin alfa 0.9 mg intramuscularly (IM) followed by a second 0.9 mg IM injection 24 hours later.

For imaging or remnant ablation, radioiodine administration should be given 24 hours following the final thyrotropin alfa injection. A post-ablation scan should be performed three to five days after radioiodine administration. A diagnostic serum thyroglobulin with or without scanning should be performed 48 hours after radioiodine administration.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code J3240 (injection, thyrotropin alpha, 0.9 mg) provided in 1.1 mg vial.

Tigecycline

Tigecycline inhibits protein translation in bacteria by binding to the 30S ribosomal subunit and blocking entry of amino-acyl tRNA molecules into the A site of the ribosome. This prevents incorporation of amino acid residues into elongating peptide chains. In general, tigecycline is considered bacteriostatic; however, tigecycline for injection has demonstrated bactericidal activity against isolates of Streptococcus pneumoniae and Legionella pneumophila.

Safety warning

All-cause mortality was higher in patients treated with tigecycline than comparators in a meta-analysis of clinical trials. Tigecycline should be reserved for use in situations when alternative treatments are not suitable.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older (J3244 only. No age restriction on J3243).

Billing

HCPCS codes:

J3243 (injection, tigecycline, 1 mg).

J3244 (injection, tigecycline [accord] not therapeutically equivalent to J3243, 1 mg)

Prescribing Restriction(s)

Frequency of billing equals100 mg/100 units, followed by 50 mg /50 units every 12 hours.

Maximum billing unit(s) equals 100 mg/100 units.

Tildrakizumab-asmn

Tildrakizumab-asmn is an interleukin-23 antagonist in solution for subcutaneous (SQ) use.

Indications

Tildrakizumab-asmn is used to treat patients with moderate-to-severe chronic plaque psoriasis (i.e. extensive and/or disabling disease) who are candidates for phototherapy or systemic therapy and when other systemic therapies are medically less appropriate.

Age

18 years and older

Dosage

100 mg SQ injection administered at weeks zero and four, and every 12 weeks thereafter.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- The service is medically necessary to treat moderate-to-severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate.
- Alternative psoriasis therapies (e.g., phototherapy, oral agents, etc.) have been tried or considered, have failed, or are contra-indicated.
- The physician's legible, complete, and signed treatment plan/order for tildrakizumab-asmn.

Billing

HCPCS code J3245 (injection, tildrakizumab-asmn, 1 mg)
One (1) unit of J3245 equals 1 mg of tildrakizumab-asmn solution

Tocilizumab

Tocilizumab is an interleukin-6 (IL-6) receptor antagonist for intravenous (IV) or subcutaneous (SQ) administration.

Indications

Tocilizumab is used to treat the following conditions:

- Rheumatoid Arthritis
- Giant Cell Arteritis
- Polyarticular Juvenile Idiopathic Arthritis
- Systemic Juvenile Idiopathic Arthritis
- Cytokine Release Syndrome

Age Limits

Must be two years and older.

Dosage

The recommended dosage varies based on the patient's treatment condition, age, laboratory measurements, and response to therapy.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for tocilizumab.

Billing

HCPCS code J3262 (injection, tocilizumab, 1 mg)
One (1) unit equals 1 mg of tocilizumab

‹‹Tofersen (QALSODY)

Tofersen is an antisense oligonucleotide that causes degradation of SOD1 mRNA through binding to superoxide dismutase 1 (SOD1) mRNA, which results in a reduction of SOD1 protein synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a neurologist with expertise in ALS.
- Patient has weakness attributable to ALS, and a confirmed diagnosis of ALS (definite or clinically probable) based on revised El Escorial World Federation of Neurology criteria, Awaji or Gold Coast criteria.
- Patient has a confirmed mutation in the superoxide dismutase 1 (SOD1) gene.
- Baseline documentation of functional ability prior to initiating treatment (e.g., muscle strength, respiratory strength, walking, climbing stairs, etc)
- Patient does not depend on invasive ventilation or tracheostomy.
- Patient was not previously treated for ALS with cellular therapies or gene therapies.

Initial authorization is for 6 months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Positive clinical response as evidenced by documentation of less functional decline from baseline, reduction in decline in respiratory strength, or reduction in decline in muscle strength, etc.
- Patient does not depend on invasive ventilation or tracheostomy.››

- ‹‹Patient has an absence of unacceptable toxicity from the drug, for example, serious myelitis and/or radiculitis, papilledema, aseptic meningitis, etc.

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9157 (injection, tofersen, 1 mg)

Required ICD-10-CM Diagnosis Codes

G12.21

Prescribing Restrictions

Frequency of billing equals 100 mg/100 units every 14 days for three doses followed by 100 mg/100 units every 28 days.

Maximum billing units equals 100 mg/100 units.››

Treprostinil

Treprostinil, 1 mg, (HCPCS code J3285) is reimbursable for patients 16 years of age or older with pulmonary hypertension. Claims require authorization.

Triamcinolone Acetonide Extended-Release Injectable Suspension (Zilretta)

Triamcinolone acetonide extended-release injectable suspension is a microsphere formulation of triamcinolone acetonide, a corticosteroid, to be administered by intra-articular injection.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Triamcinolone acetonide extended-release injection is considered medically necessary when the following criteria are met:

- For FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patients must have a diagnosis of osteoarthritis of the knee; and
- Patient must have inadequate response, intolerance or contraindication to at least two of the following:
  - Acetaminophen
  - Oral NSAIDs
  - Topical NSAIDs; and
- Patient must have treatment failure, intolerance or contraindication to short-acting, intra-articular steroid injections or adequate pain control but with drug-induced hyperglycemia
- Approval will be granted for a maximum of one dose (32 mg) of triamcinolone acetonide extended-release injection per knee per lifetime

One approval will be granted for a duration of six months. The TAR is not renewable.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J3304 (injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg)

Must use modifiers RT, LT for applicable knee(s).

Prescribing Restrictions

Frequency of billing equals no repeat administration

Maximum billing unit(s) equals 32 mg equals 32 units each knee

Triamcinolone Acetonide for Suprachoroidal Use (Xipere™)

Policy for triamcinolone acetonide injection for suprachoroidal use (HCPCS code J3299) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Triferic AVNU®

Triferic AVNU contains iron in the form of ferric pyrophosphate citrate. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Triferic Avnu is considered medically necessary when all of the following criteria are met:

- Patient must be 18 years of age or older
- Patient must have a diagnosis of hemodialysis-dependent chronic kidney disease (HDD-CKD)
  - The diagnosis of HDD-CKD is 4 or more months and patient requires hemodialysis at least three times per week
- Patient has serum ferritin less than or equal to 200 ng/mL
- Patient has Serum Transferrin Saturation (TSAT) less than or equal to 20 percent
- Patient has Hemoglobin less than 10 grams per deciliter (g/dL) or is being treated with an Erythropoiesis-Stimulating Agent (ESA) to maintain Hemoglobin at target and a TSAT of 30 percent or less and ferritin less than or equal to 500 ng/mL
- Patient is not receiving peritoneal dialysis
- Patient is not receiving home hemodialysis

Initial authorization is for 3 months

Continued treatment:

- Patient is monitored and continues to meet initial approval criteria.
- Patient has positive clinical response evidenced by mean change in hemoglobin from baseline.

Reauthorization is for 3 months

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J1445 (injection, ferric pyrophosphate citrate solution [triferic avnu], 0.1 mg of iron)

Important Billing Instructions:

Due to systems limitations, only whole numbers in units can be processed. Providers must bill for 68 units rather than 67.5 units.

Suggested ICD-10-CM Diagnosis Codes

N18.5, N18.6.

Prescribing Restriction(s)

Frequency of billing equals 6.75 mg/67.5 units at each hemodialysis session.

Maximum billing unit(s) equals 6.75 mg/67.5 units.

Triptorelin XR

Triptorelin extended-release (XR) is a gonadotropin-releasing hormone (GnRH) for intramuscular (IM) administration.

Indications

Triptorelin XR is used for the treatment of pediatric patients with central precocious puberty.

Age Limits

2 to 12 years of age.

Dosage

The recommended dose is 22.5 mg IM injection given once every 24 weeks.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR should include clinical documentation that demonstrates all of the following:

- A diagnosis of central precocious puberty (idiopathic or neurogenic) as defined by the onset of secondary sexual characteristics before the age of 8 years in girls and age 9 years in boys.
- The clinical diagnosis is confirmed by a pubertal basal level of luteinizing hormone (LH) based on the laboratory reference ranges, a pubertal response to a GnRH stimulation test, and the child's bone age is advanced one year or more beyond the child's chronologic age.
- Alternate etiologies of precocious puberty have been considered, evaluated, and ruled-out by baseline evaluation and testing such as height, weight, and height velocity; a brain MRI; gonadal and adrenal ultrasound imaging; serum levels of estrogen or testosterone; and adrenal steroids and beta human chorionic gonadotropin levels.

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

- E22.8 (Other hyperfunction of pituitary gland [central precocious puberty])

Billing

HCPCS code J3316 (injection, triptorelin extended-release, 3.75 mg)
One (1) unit of J3316 = 3.75 mg triptorelin extended-release injection solution

Ublituximab-xiiy (Briumvi™)

Ublituximab is a chimeric IgG monoclonal antibody directed against the CD20 antigen on pre-B and mature B lymphocytes. The precise mechanism by which Ublituximab exerts its therapeutic effects in multiple sclerosis is unknown, but is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, Ublituximab results in antibody-dependent cellular cytolysis and complement-mediated lysis.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with a neurologist››
- Patient has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease)
- Documentation of MRI of brain with abnormalities consistent with MS
- Greater than or equal to 2 relapses in prior 2 years or 1 relapse in the prior year and/or greater than or equal to 1 T1 gadolinium (Gd) enhancing lesion in the prior year
- No active HBV confirmed by positive results for Hepatitis B surface antigen (HBsAg) and anti-HBV tests
- Must monitor levels of immunoglobulins at the beginning, during, and after discontinuation of treatment
  - Ubilituximab is not covered in presence of documented persistent hypogammaglobulinemia, unless provider submits documentation demonstrating that there is no effective alternative treatment
- Expanded Disability Status Scale (EDSS) 0 to 5.5
- Not pregnant or nursing
- Patient does not have Primary Progressive MS (PPMS)

Initial Authorization is up to 12 months

<u>Continued Treatment</u>

Patient has experienced positive clinical response as evidenced by improvement or stability in disease activity, or slowing of disability, based on at least one of the following from baseline:

- Reduction or stabilization in the total number of magnetic resonance imaging (MRI) T1 gadolinium-enhancing lesions
- Reduction or stabilization in the total number of new or enlarging MRI T2 hyperintense lesions.
- Lack of disability progression, defined as an increase in Expanded Disability Status Scale (EDSS) score.

- Stabilization, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.

Reauthorization is up to 12 months

Age Limits

Must be 18 years and older

Billing

HCPCS code: J2329 (Injection, ublituximab-xiiy, 1mg)

Required ICD-10 Diagnosis Code

G35

Prescribing Restriction(s)

Frequency of billing initial equals 150 mg/150 units on day 1, followed by 450 mg/450 units 2 weeks after, then 450 mg/450 units every 24 weeks.

Maximum billing unit(s) equals 450 mg/450 units.

Ustekinumab

Ustekinumab is a human IgG1κ monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. Ustekinumab disrupts IL-12 and IL-23 mediated signaling and cytokine cascades.

Indications

For the treatment of adult patients 18 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Required Codes

Restricted to ICD-10-CM diagnosis code L40.0.

Dosage

Ustekinumab is administered by subcutaneous injection.

For patients weighing less than 100 kg, the recommended dose is 45 mg initially and four weeks later, followed by 45 mg every 12 weeks.

For patients weighing more than 100 kg, the recommended dose is 90 mg initially and four weeks later, followed by 90 mg every 12 weeks.

Billing

HCPCS code J3357 (ustekinumab, for subcutaneous injection, 1 mg)

Ustekinumab Intravenous

Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the shared p40 protein subunit used by both the IL-12 and IL-23 cytokines. In the pathophysiology of psoriatic inflammatory diseases IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. Levels of IL-12/23 and p40 are elevated in the skin and blood of psoriasis patients, and blood of psoriatic arthritis patients. Ustekinumab disrupts IL-12 and IL-23 mediated signaling and cytokine cascades. The cytokines IL-12 and IL-23 have been implicated as important contributors to the chronic inflammation that occurs in Crohn's disease.

Indications

Ustekinumab intravenous (I.V.) is indicated for the treatment of adult patients age 18 years of age and older with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis, alone or in combination with methotrexate.
- Moderately to severely active Crohn's disease (CD) who have failed or were intolerant to:
  - Treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or
  - Treatment with one or more TNF blockers.

Dosage

Administer Ustekinumab I.V. according to the following conditions:

Moderate to Severe Plaque Psoriasis:

- For patients weighing less than 100 kg (220 lbs), the recommended dose is 45 mg initially and four weeks later, followed by 45 mg every 12 weeks.
- For patients weighing greater than or equal to 100 kg (220 lbs), the recommended dose is 90 mg initially and four weeks later, followed by 90 mg every 12 weeks.

Active Psoriatic Arthritis:

- The recommended dose is 45 mg initially and four weeks later, followed by 45 mg every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg (220 lbs), the recommended dose is 90 mg initially and four weeks later, followed by 90 mg every 12 weeks.

Moderately to Severely Active Crohn's Disease:

Intravenous induction adult dosage regimen:

A single intravenous infusion using weight-based dosing.

- 55 kg or less: 260 mg
- More than 55 kg, up to exactly 85 kg: 390 mg
- More than 85 kg: 520 mg
- The recommended maintenance dosage is a subcutaneous 90 mg dose administered eight weeks after the initial intravenous dose, then every eight weeks thereafter.

Authorization

An approved TAR is required for reimbursement. The TAR must document that the patient has moderate to severe plaque psoriasis, active psoriatic arthritis or Crohn's disease.

Billing

HCPCS code J3358 (ustekinumab, for intravenous injection, 1 mg)

Vancomycin

Vancomycin is a glycopeptide antibiotic. The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. In addition, vancomycin alters bacterial-cell-membrane permeability and RNA synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS codes:

J3370 (injection, vancomycin HCl, 500 mg).

J3371 (injection, vancomycin hcl [mylan] not therapeutically equivalent to J3370, 500 mg).

J3372 (injection, vancomycin hcl [xellia] not therapeutically equivalent to J3370, 500 mg).

Prescribing Restriction(s)

Frequency of billing equals 2 g/4 units per 24 hours.

Maximum billing unit(s) equals 2 g/4 units.

Vasopressin

Vasopressin causes vasoconstriction by binding to V1 receptors on vascular smooth muscle coupled to the Gq/11-phospholipase C-phosphatidyl-inositol-triphosphate pathway, resulting in the release of intracellular calcium. In addition, vasopressin stimulates antidiuresis via stimulation of V2 receptors which are coupled to adenyl cyclase.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS codes:

- J2598 (Injection, vasopressin, 1 unit)
- J2599 (Injection, vasopressin (American Regent) not therapeutically equivalent to J2598, 1 unit)

Vedolizumab

Vedolizumab is a humanized IgG_1 monoclonal antibody produced in Chinese hamster ovary cells that binds to the human α4β7 integrin and blocks the interaction of α4β7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The interaction of the α4β7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis (UC) and Crohn's disease (CD).

Indications

Ulcerative Colitis:

Adult patients 18 years of age and older with moderately to severely active UC who have had an inadequate response with, lost response to or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.

Crohn's Disease:

Adult patients 18 years of age and older with moderately to severely active CD who have had an inadequate response with, lost response to or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to or demonstrated dependence on corticosteroids.

Authorization

An approved TAR is required for reimbursement.

Dosage

The recommended and maximum dosage is 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter.

Billing

HCPCS code J3380 (injection, vedolizumab, 1 mg)

Viltolarsen (Viltepso™)

Viltolarsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR/SAR Requirement

An approved *Treatment Authorization Request* (TAR) or CCS Program *Service Authorization Request* (SAR) is required for reimbursement.

TAR/SAR Criteria

Must submit clinical documentation that demonstrates the following:

- Must be prescribed for FDA-approved indications and dosages
- Patient must be 4 years of age or older
- Must be prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD. For California Children's Services (CCS) patients, must be under the supervision and monitoring of a CCS-paneled neurologist or physical medicine and rehabilitation specialist who is fellowship trained in neuromuscular medicine at a CCS Neuromuscular Medicine Special Care Center (SCC), or at a neurology clinic.
- Must have a diagnosis of Duchene Muscular Dystrophy (DMD) with mutation amenable to exon 53 skipping as documented by genetic test(s)
- The following are completed as part of the assessment for antisense oligonucleotide therapy:
  - Forced Vital Capacity (FVC)
  - Brooke score
  - six minute walk test (6MWT), if ambulatory, and
  - Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C

- The FVC is greater than 30% predicted or the Brooke score is less than or equal to 5
- Only one antisense oligonucleotide treatment shall be authorized at a time
- Patient is on a corticosteroid, or has documented medical reason not to be on this medication
- Patient must start on the less expensive, equivalent or superior drug
- Continuation of a more expensive alternative must be justified with a compelling reason for doing so
- For CCS patients, CCS Neuromuscular Medicine SCC or CCS-paneled neurologist has included the following supporting documentation in the medical record:
  - Documentation of recent FVC.
  - Brooke Score or baseline 6MWT if ambulatory.
  - Laboratory indicator of renal function

Initial approval is for 12 months.

Reauthorization

- Patient has finished the initial course and has not had significant decline in FVC beyond the pre-treatment disease trajectory while on the antisense oligonucleotide treatment
- Motor function has improved or has not declined beyond pretreatment trajectory, evidenced by improved or maintained score in 6MWT, timed function tests, Performance of Upper Limb (PUL), Brooke score, other standardized assessment of motor function, or quantifiable description of improvement by the physician or physical therapist in the medical record
- Patient has not experienced significant adverse effects attributable to viltolarsen
- Patients with a FVC score of less than or equal to 30 percent and Brooke score of six will not be granted authorizations because, at the time of this policy, there is insufficient evidence of efficacy in that population

Additional consideration for medical necessity determination:

- For CCS patients who do not meet the criteria described above, SCCs may also submit other clinical documentation and/or evidence that would support the medical necessity for initial or reauthorization of the patient's antisense oligonucleotide treatments. SCCs should submit this documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee.

Reauthorization is for 12 months.

Policy Implementation for CCS Patients

‹‹A. Submissions of authorization requests for eteplirsen, golodirsen, or viltolarsen are not included in Service Code Groupings.››

1. For clients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
2. For clients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at CCSExpeditedReview@dhcs.ca.gov or via secure RightFax (916) 440-5306

B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding the policy for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

After the transition of pharmacy benefit to Medi-Cal RX in 2021, all requests for prior authorization of medications billed by National Drug Code and dispensed by a Medi-Cal enrolled pharmacy provider, shall be sent from the pharmacy provider to the Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (Magellan). The Medi-Cal RX website provides guidance: https://medi-calrx.dhcs.ca.gov/home/.

Age Limit

Must be four years of age or older

Billing

HCPCS code J1427 (injection, viltolarsen, 10mg)

Suggested ICD-10-CM Codes

G71.01

Prescribing Restrictions

Frequency of billing equal 80 mg/kg once every seven days

Deletions That May Be Amenable to Exon Skipping

The list displays common Duchenne Muscular Dystrophy (DMD) deletions that are potentially amenable to exon skipping.

Exon Deletions Potentially Amenable to Exon 51

3-50	19-50	33-50	47-50
4-50	21-50	34-50	48-50
5-50	23-50	35-50	49-50
6-50	24-50	36-50	50
9-50	25-50	37-50	52
10-50	26-50	38-50	52-58
11-50	27-50	39-50	52-61
13-50	28-50	40-50	52-63
14-50	29-50	41-50	52-64
15-50	30-50	42-50	52-76
16-50	31-50	43-50	52-77
17-50	32-50	45-50	

Exon Deletions Potentially Amenable to Exon 53

3-52	19-52	33-52	47-52
4-52	21-52	34-52	48-52
5-52	23-52	35-52	49-52
6-52	24-52	36-52	50-52
9-52	25-52	37-52	52
10-52	26-52	38-52	54-58
11-52	27-52	39-52	54-61
13-52	28-52	40-52	54-63
14-52	29-52	41-52	54-64
15-52	30-52	42-52	54-66
16-52	31-52	43-52	54-76
17-52	32-52	45-52	54-77

Voretigene neparvovec-rzyl

Voretigene neparavovec-rzyl is an adeno-associated virus vector-based gene therapy for injection into the retina of the eye.

Indications

Voretigene neparvovec-rzyl is used for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

Age

1 to 64 years of age

Dosage

1.5 by 10^{11} vector genomes (vg) administered into one eye by subretinal injection. If both eyes require treatment, each eye should be injected on separate days within a close interval, but no fewer than 6 days apart.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

The TAR must include clinical documentation that demonstrates all of the following:

- The service is medically necessary to treat retinal dystrophy due to confirmed RPE65 mutation(s) in both alleles by molecular pathology report;
- The patient has viable retinal cells in the eye indicated for treatment as determined by:
  - an area of retina within the posterior pole of greater than 100 µm thickness measured by OCT (optical coherence tomography); or
  - Equal to or greater than 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole (a “disc area” is equivalent to the area of the optic disc); or
  - A remaining visual field within 30 degrees of fixation as measured by a III43 isopter or equivalent.
- The physician’s legible, complete, and signed treatment plan/order for voretigene neparvovec-ryzl.

Required Codes

One of the following ICD-10-CM diagnosis codes is required for reimbursement:

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

Billing

HCPCS code J3398 (injection, voretigene neparvovec-rzyl, one billion vector genomes).

One (1) unit of J3398 equals one billion voretigene neparvovec-rzyl vector genomes.

Vutrisiran (AMVUTTRA™)

Vutrisiran is a double-stranded small interfering ribonucleic acid (siRNA)-N-acetylgalactosamine (GalNAc) conjugate that causes degradation of mutant and wild-type transthyretin (TTR) messenger ribonucleic acid (RNA) (mRNA) through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be for FDA-approved indications and dosing regimens
- Must be 18 years of age or older
- Must be prescribed by or in consultation with a neurologist, hematologist, cardiologist, geneticist, or a physician who specializes in the treatment of amyloidosis
- Patient has a diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with documented mutation in transthyretin (TTR) gene; or tissue biopsy results consistent with amyloid deposition.

- Patient has clinical signs and symptoms of the disease (for example, peripheral sensorimotor neuropathy, autonomic neuropathy, motor disability, etc.)
- Patient had one of the following test results at baseline:
  - Neuropathy Impairment Score of (five to 130)
  - Polyneuropathy disability (PND) score stage 3B or less (equal to or less than IIIb)
- Other causes of peripheral neuropathy have been ruled out
- Patient has not had a liver transplant and is not planning to undergo one.
- Patient is receiving supplementation with vitamin A at the recommended daily allowance.
- Patient is not currently taking diflunisal, tafamidis, doxycycline, or inotersen.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial coverage criteria
- Patient has shown clinical improvement or lack of disease progression from baseline as evidenced by at least one of the following:
  - Improvement in neurologic impairment or motor function
  - Improvement or stability in Neuropathy Impairment score, or Polyneuropathy disability (PND) score

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0225 (injection, vutrisiran, 1 mg).

Required ICD-10 Diagnosis Code

E85.1

Prescribing Restriction(s)

Frequency of billing equals 25 mg/ 25 units.

Maximum billing unit(s) equals 25 mg/25 units once every three months.

Ziprasidone

Ziprasidone is reimbursable for acute and long-term treatment of adult schizophrenia.

Ziprasidone has been shown to be effective for the acute and long-term management of agitation experienced by patients with schizophrenia.

Note: There is a Food and Drug Administration warning on ziprasidone about its greater capacity to prolong the QT/QTc intervals as opposed to other antipsychotic drugs. Prolongation of the QTc interval has been associated with the development of a potentially fatal condition of ventricular tachycardia and sudden death.

Dosage

The maximum dosage is 40 mg per day.

Billing

For billing ziprasidone mesylate, 10 mg injection, use HCPCS code J3486.

Zoledronic Acid

Zoledronic acid is a bisphosphonic acid which is an inhibitor of osteoclastic bone resorption. Although the antiresorptive mechanism is not completely understood, several factors are thought to contribute to this action. In vitro, zoledronic acid inhibits osteoclastic activity and induces osteoclast apoptosis. It also blocks the osteoclastic resorption of mineralized bone and cartilage through its binding to bone. Finally, it inhibits the increased osteoclastic activity and skeletal calcium release induced by various stimulatory factors released by tumors.

Indications

Zoledronic acid is used for both malignant and non-malignant conditions and is indicated for the treatment of:

- Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.
- Prevention of postmenopausal osteoporosis
- Osteoporosis in men
- Prevention of glucocorticoid-induced osteoporosis
- Paget’s disease of bone in men and women
- Hypercalcemia of malignancy

Dosage

The dose varies depending upon which disease or condition is being treated.

Billing

HCPCS code J3489 (injection, zoledronic acid, 1 mg).

For the use of zoledronic acid in non-malignant conditions, coverage is limited to one 5 mg injection, once every 12 months.

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.