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

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

Sargramostim is indicated for use:

- Following induction chemotherapy in acute myelogenous leukemia
- In mobilizing and following transplantation of autologous peripheral blood progenitor cells
- In myeloid reconstitution after autologous or allogeneic bone marrow transplantation
- In bone marrow transplantation failure or engraftment delay
- In neutropenia induced by chemotherapy

Dosage

The recommended dose varies according to the condition being treated. Please see the appropriate medical literature for details.

Required Codes

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

D70.1	Z51.89
D70.2	Z94.81
Z51.11	Z94.84

Billing

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

Sebelipase Alfa

Sebelipase alfa is a hydrolytic lysosomal cholsteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of lysosomal acid lipase deficiency (LAL-D).

Dosage

Patients with rapidly progressive LAL-D presenting within the first six months of life

The recommended dosage is 1 mg/kg as an intravenous infusion once per week. For patients who do not achieve an optimal clinical response, increase to 3 mg/kg once per week.

Pediatric and adult patients with LAL-D

The recommended dosage is 1 mg/kg as an intravenous infusion once every other week.

Required Code

ICD-10-CM diagnosis code E77.0

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)

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 - 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.

‹‹Teprotumumab-trbw

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
- Patient must be less than 9 months from the onset of TED symptoms
- Patient must be euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine and free triiodothyronine levels less than 50% 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
- Patient has a contraindication, intolerance, or lack of response to glucocorticoids

Authorization is for 6 months (a maximum of 8 infusions).

Continued Therapy

- Patient continues to meet initial coverage criteria
- Patient is responding positively to therapy as evidenced by a greater than or equal to 2 point reduction in CAS from baseline and a greater than or equal to 2 mm reduction in proptosis from baseline
- Patient continues to have active TED with a CAS of greater than or equal to 3

Reauthorization is for 6 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= 10 mg/kg initial dose, then 20 mg/kg every 3 weeks for 7 additional doses››

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, 1 mg (HCPCS code J3243) has a maximum daily dosage of 100 mg.

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.

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 0 and 4, 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 = 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

2 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 = 1 mg of tocilizumab

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 = no repeat administration

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

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

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

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 <100 kg, the recommended dose is 45 mg initially and four weeks later, followed by 45 mg every 12 weeks.

For patients weighing >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 <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 ≥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 >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 that is reimbursable when used for the treatment of serious or severe infections caused by susceptible strains of gram positive bacteria.

Dosage

The initial intravenous dose should be based on actual body weight, with subsequent dosing based on serum trough vancomycin concentrations.

Billing

HCPCS code J3370 (injection, vancomycin HCl, 500 mg)
One (1) unit = 500 mg

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)

Vestronidase alfa-vjbk (Mepsevii™)

Mepsevii (vestronidase alfa-vjbk) is a recombinant human lysosomal beta glucuronidase. Mucopolysaccharidosis VII (MPS VII or Sly syndrome) is a lysosomal storage disorder caused by deficiency of an enzyme called beta-glucuronidase, which causes an abnormal buildup of toxic materials in the body's cells. Mepsevii is an enzyme replacement therapy that works by replacing the missing enzyme.

Indications

All FDA-approved investigations

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Mepsevii will be considered medically necessary if the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 5 months or older
- Patient must have a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) confirmed by both of the following:
  - Leukocyte or fibroblast glucuronidase enzyme assay
  - Detection of pathogenic mutations in the GUSB gene by molecular genetic testing
- Patient must have at least one of the following documented at baseline:
  - Elevated glycosaminoglycans (uGAG) excretion at a minimum of 3-fold over the mean normal for age (at Screening)
  - Bruininks-Oseretsky Test (BOT-2) of Motor Proficiency
  - Shoulder flexion as a measure of limited joint range of motion (ROM)
  - Airway obstruction or pulmonary problems shown by Forced vital capacity (FVC) from pulmonary function testing (PFT),
  - Enlarged liver and/or spleen
  - Limitation of mobility while still ambulatory; confirmed by six-minute walk test (6MWT) or other standard mobility/endurance tests

Initial approval is for 12 months.

<u>Continued therapy:</u>

- Patient continues to meet the Initial approval criteria
- Patient has shown positive clinical response to therapy from baseline as evidenced by at least one of the following:
  - Reduction in uGAGs excretion.
  - Improvement or stabilization in 6MWT or other standard mobility/endurance test
  - Improvement or stabilization in FVC
  - Reduction in liver and/or spleen volume
  - Improvement or stabilization in joint range of motion
  - Improvement or stabilization in motor skills (BOT-2)

Reauthorization is for 12 months.

Age Limits

Must be 5 months or older.

Billing

HCPCS code J3397 (injection, vestronidase alfa-vjbk, 1 mg)

Suggested ICD-10-CM Diagnosis Codes

E76.29

Prescribing Restriction(s)

Frequency of billing equals 4 mg/kg every 14 days

‹‹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
  - 6 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.
- For CCS patients, CCS Neuromuscular Medicine SCC or CCS-paneled neurologist has provided a completed Antisense Oligonucleotide Request Form (see link below) that includes the following information:
  - 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 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. Until the transition of pharmacy benefit to Medi-Cal Rx, providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation,and clinical progress notes from a visit within the past 6 months.

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.

Beginning April 1, 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

Must be four years of age or older

Billing

HCPCS code C9071 (injection, viltolarsen, 10mg)

Suggested ICD-10-CM Codes

G71.01

Prescribing Restrictions

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

‹‹Service Authorization Request Tools

https://www.dhcs.ca.gov/services/ccs/cmsnet/Pages/SARTools.aspx#service
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, 1 billion vector genomes)

One (1) unit of J3398 = 1 billion voretigene neparvovec-rzyl vector genomes

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.