Injections: Drugs G Policy

Page updated: March 2024

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:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs C Policy*
- *Injections: Drugs D Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs J-L Policy*
- *Injections: Drugs M Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

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Ganciclovir Injection (GANZYK-RTU)

Ganciclovir is phosphorylated by viral and cellular kinases into ganciclovir triphosphate which competitively inhibits the binding of deoxyguanosine triphosphate to DNA polymerase resulting in inhibition of viral DNA synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

Universal Criteria

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years and older.
- Ganciclovir is being used under one of the following conditions:
  - Patient is immunocompromised or has acquired immunodeficiency syndrome (AIDS) and ganciclovir is being used for the treatment of cytomegalovirus (CMV) retinitis.
  - Patient is a transplant recipient at risk for CMV and ganciclovir is being used for the prevention of CMV disease.
- Patient has no history of hypersensitivity to acyclovir or ganciclovir.
- Oral antiviral products (for example, valganciclovir, ganciclovir, etc.) are not clinically appropriate.

Patient must meet A or B below:

A. Treatment of CMV Retinitis

- Patient is immunocompromised or has AIDS and has a diagnosis of CMV retinitis by ophthalmologic examination.

B. Prevention of CMV Disease in Transplant Recipients

- Patient meets one of the following criteria:
  - Patient is an organ transplant recipient and is at risk of CMV infection (CMV seropositive or a seronegative recipient of an organ from a CMV seropositive donor).
  - Patient is a bone marrow recipient with asymptomatic CMV infection (CMV positive culture of urine, throat or blood)
  - Patient is an allogeneic bone marrow transplant recipient at risk for CMV disease (Patients with histologic, immunologic or virologic evidence of CMV infection in the lung post-transplant)

Authorization is for six months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1574 (injection, ganciclovir sodium [exela] not therapeutically equivalent to J1570, 500 mg).

GenVisc 850®

GenVisc 850 is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate (average of 850,000 daltons and a range of 620,000 to 1,170,000 daltons) having a pH of 6.8 to 7.8. Each 2.5 ml of GenVisc 850 contains 10 mg/ml of sodium hyaluronate dissolved in a physiological saline (1.0 percent solution). The sodium hyaluronate is derived from bacterial fermentation. Sodium hyaluronate is a poly-saccharide containing repeating disaccharide units of glucuronic acid and N-acetylglucosamine.

Indication

GenVisc 850 is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative, non-pharmacologic therapy and simple analgesics, such as acetaminophen.

Dosage

GenVisc 850 is administered by intra-articular injection. A treatment cycle consists of five injections given at weekly intervals. Strict aseptic administration technique must be followed. Inject the full 2.5 ml in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.

Required Codes

ICD-10-CM diagnosis codes:

M17.0	M17.2	M17.4
M17.10	M17.30	M17.5
M17.11	M17.31	M17.9
M17.12	M17.32	

Billing

HCPCS code J7320 (hyaluronan or derivative, genvisc 850, for intra-articular injection 1 mg).

Givosiran (Givlaari®)

Givosiran causes degradation of aminolevulinate synthase 1 (ALAS1) messenger RNA (mRNA) in hepatocytes through RNA interference, reducing the elevated levels of liver ALAS1 mRNA. This leads to reduced circulating levels of neurotoxic intermediates aminolevulinic acid and porphobilinogen, factors associated with attacks and other disease manifestations of acute hepatic porphyria.

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 dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a hematologist, neurologist, gastroenterologist, or other provider with expertise in Acute Hepatic Porphyria (AHP).
- Patient has a diagnosis of AHP (Acute Intermittent Porphyria [AIP), Hereditary Corproporhyria [HCP], Variegate Porphyria [VP], aminolevulinic acid [ALA] dehydratase deficient porphyria [ADP]).

- Genetic testing results was according to 1 or 2 below:
    1. Shows evidence of mutation in a porphyria-related gene, defined as ANY of the following:
        - ❖ AIP: mutation in the hydroxymethylbilane synthase gene (HMBS; also referred to as the orphobilinogen deaminase [PBGD] gene)
        - ❖ HCP: mutation in the coproporphyrinogen oxidase (CPOX) gene
        - ❖ VP: mutation in the protoporphyrinogen oxidase (PPOX) gene
        - ❖ ADP: mutation in the aminolevulinic acid dehydratase (ALAD) homozygous or compound heterozygous genes; OR
    2. Does not identify a mutation in a porphyria-related gene (less than 5 percent of cases), but patient has both clinical features and diagnostic biochemical criteria consistent with AHP.
- Patient has at least one documented urinary or plasma porphobilinogen (PBG) or ALA values within the 12 months.
- Patient has active disease, with at least two documented porphyria attacks within prior six months requiring hospitalization, urgent healthcare visit OR
    - Patient requires hemin prophylaxis to prevent this frequency of attacks
- Patient does not have any of the following:
    - A clinically significant abnormal laboratory results, including renal and hepatic function tests.
    - Anticipated liver transplantation

Initial authorization is for 12 months.

<u>Continued therapy:</u>

- Patient continues to meet the initial approval criteria.
- Patient has shown clinical benefit as evidenced by at least <u>one</u> of the following:
    - Reduction in the rate of porphyria attacks requiring hospitalizations, urgent healthcare visit, or intravenous hemin administration at home
    - Reduction in ALA or PBG levels from baseline

- Improvement in signs and symptoms of AHPs (for example, neurological, peripheral neuropathy, abdominal pain, muscle aches, weakness, etc.)
- Patient shows absence of unacceptable toxicity from the drug (e.g., severe or clinically significant hepatic toxicity [transaminase elevations], severe renal toxicity [increases in serum creatinine levels and decreases in estimated glomerular filtration rate eGFR], etc.)

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J0223 (injection, givosiran, 0.5 mg)

Suggested ICD-10 Diagnosis Codes

E80.20, E80.21, E80.29

Prescribing Restrictions

Frequency of billing equals 2.5 mg/kg every month.

Claims must include an invoice showing the cost of the drug.

Glucagon

Glucagon increases blood glucose concentration by activating hepatic glucagon receptors, thereby stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for glucagon to produce an antihypoglycemic effect. Extrahepatic effects of glucagon include relaxation of the smooth muscle of the stomach, duodenum, small bowel, and colon.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

J1610 (injection, glucagon hydrochloride, per 1 mg).

J1611 (injection, glucagon hydrochloride [fresenius kabi], not therapeutically equivalent to J1610, per 1 mg).

Glucarpidase

Glucarpidase is a carboxypeptidase produced by recombinant DNA technology in genetically modified *Escherichia coli*. It hydrolyzes the carboxyl-terminal glutamate residue from folic acid and classical antifolates such as methotrexate and converts it to its inactive metabolites 4-deoxy-4-amino-N10-methylpteroic acid (DAMPA) and glutamate. Glucarpidase provides an alternate non-renal pathway for methotrexate elimination in patients with renal dysfunction during high-dose methotrexate treatment.

Indications

Glucarpidase is indicated for the treatment of toxic plasma methotrexate concentrations (less than 1 micromole per liter) in patients with delayed methotrexate clearance due to impaired renal function.

Limitation of Use

Glucarpidase is not indicated for use in patients who exhibit the expected clearance of methotrexate (plasma methotrexate concentrations within two standard deviations of the mean methotrexate excretion curve specific for the dose of methotrexate administered) or those with normal or mildly impaired renal function because of the potential risk of subtherapeutic exposure to methotrexate.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. Clinical information submitted with the TAR must confirm that the drug is being used only for the indication above and is in agreement with the stated limitation of use.

Dosage

A single intravenous injection of 50 units per kg.

Billing

HCPCS code C9293 (injection, glucarpidase, 10 units).

‹‹Glycopyrrolate››

Glycopyrrolate, like other anticholinergic (antimuscarinic) agents, inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are present in the autonomic effector cells of smooth muscle, cardiac muscle, the sinoatrial node, the atrioventricular node, exocrine glands and, to a limited degree, in the autonomic ganglia. Thus, it diminishes the volume and free acidity of gastric secretions and controls excessive pharyngeal, tracheal, and bronchial secretions.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

J1596 (injection, glycopyrrolate, 0.1 mg).

‹‹J1597 (injection, glycopyrrolate (glyrx-pf), 0.1 mg).

J1598 (injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg).››

Golimumab (Intravenous)

Golimumab is a human IgG monoclonal antibody specific for human tumor necrosis factor (TNF) alpha, and binds to both the soluble and transmembrane bioactive forms of human TNF alpha. Elevated TNF alpha levels in the blood, synovium and joints have been implicated in the pathophysiology of rheumatoid arthritis (RA). TNF alpha is an important mediator of the articular inflammation that is characteristic of RA. The binding of golimumab to TNF alpha prevents the binding of TNF alpha to its receptors, thereby inhibiting its biological activity.

Indications

Golimumab, in combination with methothetrexate, is indicated for adult patients 18 years of age and older with moderate to severely active RA.

Authorization

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

Dosage

The recommended dose is 2 mg/kg given as an intravenous infusion over 30 minutes at weeks zero and four, then every eight weeks.

Billing

HCPCS code J1602 (injection, golimumab, 1 mg).

One (1) billed unit equals the entire dose administered.

‹‹**Note**: Providers must document the patient’s current weight.››

Golodirsen (Vyondys 53™)

Golodirsen 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 California Children's Services (CCS) Program *Service Authorization Request* (SAR) is required for reimbursement.

TAR/SAR Criteria

A. Initial Authorization

Golodirsen is both a Medi-Cal and CCS Program benefit when the following criteria are met:

1. Patient must be two years of age or older.
2. Patient has documented Duchenne muscular dystrophy (DMD) with dystrophin gene mutation, amenable to exon 53 skipping documented by genetic test(s).
3. Care is under the supervision and monitoring of a neurologist; or for CCS patients, 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 a neurology clinic.
4. The following are completed as part of the assessment for antisense oligonucleotide therapy:
   a) Forced vital capacity (FVC)
   b) Brooke score
   c) Six-minute walk test (6MWT), if ambulatory, and
   d) Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C

5. The FVC is greater than 30 percent predicted OR the Brooke score is less than or equal to five.
6. Request for antisense oligonucleotide therapy is for the FDA-approved dosage only.
7. Only one antisense oligonucleotide treatment shall be authorized at a time.
8. Patient is on a corticosteroid or has documented reason not to be on this medication.

Initial authorization is for up to 12 months.

B. Reauthorization

Golodirsen shall be reauthorized for up to 12 months when the patient has finished the initial course of treatment and all of the following apply:

1. Patient has not had significant decline in FVC beyond the pre-treatment disease trajectory while on the antisense oligonucleotide treatment.
2. Motor function has improved, or has not declined beyond pre-treatment trajectory, evidenced by improved or maintained score in 6MWT, time 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.
3. Patient has not experienced significant adverse effects attributable to golodirsen.

C. Patients with FVC less than or equal to 30 percent and Brooke Score of six may not be granted TAR/SAR authorizations because at the time of this policy, there is insufficient evidence of efficacy in that population.

D. Additional consideration for medical necessity determination. For patients who do not meet the criteria described in sections A. or B 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.

Policy Implementation for CCS Patients

A. Submission of authorization requests for golodirsen are not included in Service Code Groupings (SCGs)
   1. For patients 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 patients 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 documents to the DHCS ISCD Special Populations Authorization Unit e-mail at CCSOperations@dhcs.ca.gov or via secure RightFax at (916) 440-5768.

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

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

Age Limit

Must be two years of age or older.

Billing

HCPCS code J1429 (injection, golodirsen, 10 mg).

Required ICD-10 Diagnosis Codes

G71.01

Prescribing Restrictions

Frequency of billing equals 30 mg/kg once weekly.

Granisetron

Granisetron is a selective 5-hydroxytryptamine3 (5-HT3) receptor antagonist with little or no affinity for other serotonin receptors.

Indications

Granisetron injection is indicated for:

- The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy.
- The prevention and treatment of postoperative nausea and vomiting in adults. As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided during the postoperative period granisetron injection is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Dosage

For the prevention of chemotherapy-induced nausea and vomiting, the recommended dosage for granisetron injection is 10 mcg/kg administered intravenously within 30 minutes before initiation of chemotherapy, and only on the day(s) chemotherapy is given. Medical justification is required when the dosage exceeds 1,400 mcg.

For the prevention of postoperative nausea and vomiting, the recommended dosage is 1,000 mcg of granisetron, undiluted, administered intravenously over 30 seconds, before induction of anesthesia or immediately before reversal of anesthesia. The recommended dosage for the treatment of nausea and/or vomiting after surgery is 1,000 mcg of granisetron undiluted, administered intravenously over 30 seconds.

Billing

HCPCS code J1626 (injection, granisetron HCl, 100 mcg).

Granisetron Extended Release (Sustol®)

Granisetron extended release injection is a serotonin-3 (5-HT3) receptor antagonist with little or no affinity for other serotonin receptors. Serotonin receptors of the 5-HT3 type are located peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. During chemotherapy-induced vomiting, mucosal enterochromaffin cells release serotonin, which stimulates 5-HT3 receptors. This evokes vagal afferent discharge and may induce vomiting. Animal studies demonstrate that, in binding to 5-HT3 receptors, granisetron blocks serotonin stimulation and subsequent vomiting after emetogenic stimuli such as cisplatin. In the ferret animal model, a single granisetron injection prevented vomiting due to high-dose cisplatin or arrested vomiting within 5 to 30 seconds.

Indications

All FDA-approved indications.

Dosage

All 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.
- Patient is scheduled to undergo cancer chemotherapy.
- Sustol is being used in combination with other antiemetics (for example aprepitant or fosaprepitant, and dexamethasone or olanzapine, etc) for the prevention of acute and delayed nausea and vomiting associated with one of the following:
  - Initial and repeat courses of moderately emetogenic chemotherapy (MEC)
  - Anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Authorization is for six months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1627 (injection, granisetron extended release, 0.1 mg).

Suggested ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes: R11.0, R11.10, R11.11, R11.12, R11.2, and Z51.11

Prescribing Restriction(s)

Frequency of billing equals 10 mg/100 units once every seven days.

Maximum billing unit(s) is 10 mg/100 units.

Granisetron HCL

Granisetron is a selective 5-hydroxytryptamine3 ($5\text{-}HT_3$) receptor antagonist with little or no affinity for other serotonin receptors.

Indications

Granisetron injection is indicated for:

- The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy.
- The prevention and treatment of postoperative nausea and vomiting in adults. As with other antiemetics, routine prophylaxis is not recommended in patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided during the postoperative period granisetron injection is recommended even where the incidence of postoperative nausea and/or vomiting is low.

Dosage

For the prevention of chemotherapy-induced nausea and vomiting, the recommended dosage for granisetron injection is 10 mcg/kg administered intravenously within 30 minutes before initiation of chemotherapy, and only on the day(s) chemotherapy is given. Medical justification is required when the dosage exceeds 1,400 mcg.

For the prevention of postoperative nausea and vomiting, the recommended dosage is 1,000 mcg of granisetron, undiluted, administered intravenously over 30 seconds, before induction of anesthesia or immediately before reversal of anesthesia. The recommended dosage for the treatment of nausea and/or vomiting after surgery is 1,000 mcg of granisetron undiluted, administered intravenously over 30 seconds.

Billing

HCPCS code J1626 (injection, granisetron HCl, 100 mcg).

Growth Hormone Injections

For information about the use of growth hormone injections for HIV-associated wasting, see “Somatropin for HIV-Associated Wasting” in the *Injections: Drugs S Policy* section in this manual.

Guselkumab

Guselkumab is an interleukin-23 blocker solution for subcutaneous (SQ) use.

Indications

Guselkumab injection is used for the treatment of moderate-to-severe chronic plaque psoriasis (i.e. extensive and/or disabling disease) who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.

Age Limit

Must be 18 years of age and older.

Dosage

The recommended dose is 100 mg SQ injection administered at weeks zero and four, and every eight weeks thereafter.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative, conventional therapy has been tried or considered, has failed, or is contra-indicated.
- The physician’s legible, complete, and signed treatment plan/order for guselkumab.

Billing

HCPCS code J1628 (injection, guselkumab, 1 mg).

One (1) unit of J1628 equals 1 mg of guselkumab solution.

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.