

## Injections: Drugs E-H Policy

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 I–M Policy*
- *Injections: Drugs N–R Policy*
- *Injections: Drugs S–Z Policy*
- *Injections: Hydration*
- *Immunizations*

### **Ecallantide**

Hereditary angioedema (HAE) is a rare genetic disorder caused by mutations to C1-esterase-inhibitor (C1-INH) located on chromosome 11q and inherited as an autosomal dominant trait. HAE is characterized by low levels of C1-INH activity and low levels of C4. C1-INH functions to regulate the activation of the complement and intrinsic coagulation pathways and is a major endogenous inhibitor of plasma kallikrein. The kallikrein-kinin system is a complex proteolytic cascade involved in the initiation of both inflammatory and coagulation pathways. One critical aspect of this pathway is the conversion of High Molecular Weight (HMW) kininogen to bradykinin by the protease plasma kallikrein. In HAE, normal regulation of plasma kallikrein activity and the classical complement cascade is therefore not present. During attacks, unregulated activity of plasma kallikrein results in excessive bradykinin generation. Bradykinin is a vasodilator which is thought by some to be responsible for the characteristic HAE symptoms of localized swelling, inflammation and pain.

Ecallantide is a potent selective, reversible inhibitor of plasma kallikrein that binds to plasma kallikrein and blocks its binding site, inhibiting the conversion of HMW kininogen to bradykinin. By directly inhibiting plasma kallikrein, ecallantide reduces the conversion of HMW kininogen to bradykinin and thereby treats symptoms of the disease during acute episodic attacks of HAE.

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Indications	Ecallantide is indicated for the treatment of acute attacks of hereditary angioedema in patients 12 years of age and older.
Diagnosis Restrictions	Restricted to ICD-9-CM diagnosis code 277.6.
Dosage	The recommended dose is 30 mg administered subcutaneously in three 10 mg injections. If the attack persists, an additional dose of 30 mg may be administered within a 24-hour period.
Billing	HCPCS code J1290 (injection, ecallantide, 1 mg) One billing unit = 1 mg

**Eculizumab** Policy for eculizumab (HCPCS code J1300) is located in the *Chemotherapy: Drugs E-O Policy* section of the Part 2 manual.

**Enzyme Replacement Drugs** In the early 1960s, the first lysosomal storage disease was identified. Since then over 40 such diseases have been reported. The common feature is that enzyme deficiency leads to accumulation of undegraded macromolecules and lysosomal engorgement, resulting in organ dysfunction. Enzyme replacement drugs have been developed for many of these diseases. The following enzyme replacement drugs are benefits of the Medi-Cal program:

- Agalsidase Beta
- Alglucosidase Alfa (Lumizyme, Myozyme)
- Galsulfase
- Idursulfase
- Imiglucerase
- Laronidase
- Velaglucerase alfa

Authorization requirements for enzyme replacement drugs are described below. On the following pages the drugs are listed individually with information about their usage, dosage and billing requirements.

**Note:** Pharmacy providers of enzyme replacement therapy drugs may bill Medi-Cal directly using the NDC for the medication. This is a special Assignment of Benefit (AOB) exception to the DHCS policy restricting the reimbursement of all physician administered drugs to physicians and clinics. Pharmacy providers must submit a *Treatment Authorization Request* (TAR) to the Los Angeles Medi-Cal Field Office, with the supporting documentation listed below. In addition the pharmacy must include on the TAR the name of the physician to whom the medication will be released, or the name of the authorized representative specifically identified by the prescribing physician to receive the medication on his/her behalf. Pharmacies may not release the medication to anyone other than the prescribing physician without documented authorization from the prescribing physician identifying the specific agent authorized to receive the medication.

#### Authorization

An approved TAR is required for reimbursement for each of these drugs. The TAR must be submitted to the Los Angeles Medi-Cal Field Office.

For the initial TAR the following supporting documentation must be submitted:

- Subjective findings (complaints)
- Objective findings (exams, lab results)
  - Enzyme levels or other laboratory testing
  - DNA mutation analysis
  - Medical history
  - Physical examination
- Complications (for example, bony changes or kidney failure)
- Quality of life issues (for example, severe, unremitting pain or extreme fatigue)

- Identified licensed practitioner who will administer infusion therapy, coordinate care, and their
  - Plan: Include the treatment plan including the genetic evaluation and counseling information for the recipient and family members.
  - Goal: Include specific information about the desired outcome; for example, to slow the progression of the disease, to allow regular attendance at work or school or to significantly improve the quality of life.

Initial TAR approval may be for up to six months and renewal TARs may be approved for up to one year. Renewal TARs must include follow-up information such as any significant changes in physical findings, laboratory parameters, symptoms and/or quality of life.

#### Agalsidase Beta

Fabry disease is an X-linked genetic disorder of glycosphingolipid metabolism. Deficiency of the lysosomal enzyme alpha-galactosidase-A leads to progressive accumulation of glycosphingolipids, predominantly GL-3, in many body tissues, starting early in life and continuing over decades. Agalsidase beta is a recombinant form of the enzyme alpha-galactosidase-A, which is required for the hydrolysis of GL-3 and other glycosphingolipids. In clinical trials of limited duration, agalsidase been noted to reduce tissue inclusions of GL-3. It is believed that long-term enzyme replacement may reduce clinical manifestations of renal failure, cardiomyopathy, and stroke.

#### Indications

For use in patients with Fabry disease.

#### Authorization

The TAR must include a diagnosis of Fabry disease. For other TAR requirements, see “Authorization” near the beginning of the “Enzyme Replacement Drugs” topic in this section.

#### Dosage

The recommended dose is 1 mg/kg every two weeks.

#### Billing

HCPCS code J0180 (injection, agalsidase beta, 1 mg).

Alglucosidase Alfa  
(Lumizyme, Myozyme)

Pompe disease is an inherited disorder of glycogen metabolism caused by the absence or marked deficiency of the enzyme lysosomal acid maltase (alfa glucosidase). In the infantile-onset form, Pompe disease results in intralysosomal accumulation of glycogen in various tissues, particularly cardiac and skeletal muscles, and hepatic tissues, leading to the development of cardiomyopathy, progressive muscle weakness, and impairment of respiratory function. In the juvenile and adult-onset forms, intralysosomal accumulation of glycogen is limited primarily to skeletal muscle, resulting in progressive muscle weakness. Death in all forms is usually related to respiratory failure. Alglucosidase alfa provides an exogenous source of the enzyme lysosomal acid maltase.

Indications

- Lumizyme is used for treatment of all recipients with Pompe disease.
- Myozyme is used for treatment of recipients younger than 8 years of age with infantile onset Pompe disease.

Authorization

The TAR must include a diagnosis of Pompe disease. For other TAR requirements, see “Authorizations” near the beginning of the “Enzyme Replacement Drugs” topic in this section.

Dosage

The recommended dose is 20 mg/kg every two weeks.

Billing

HCPCS code J0220 (injection, alglucosidase alfa, 10 mg, not otherwise specified) (Use this code for Myozyme).

HCPCS code J0221 (injection, alglucosidase alfa, [Lumizyme], 10 mg).

The correct National Drug Code (NDC) must be included on claims in order to correctly price the drug.

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Galsulfase

Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome) is characterized by the absence or marked reduction in N-acetylgalactosamine-4-sulfatase. The sulfatase deficiency results in accumulation of partially degraded glycosaminoglycans, dermatan sulfate, and chondroitin 4-sulfate. This accumulation leads to widespread cellular, tissue, and organ dysfunction. Inheritance is autosomal recessive. Galsulfase is intended to provide an exogenous enzyme that will be taken up into lysosomes and increase the catabolism of glycosaminoglycans.

Indications

For use in patients with Mucopolysaccharidosis VI.

Authorization

The TAR must include a diagnosis of Mucopolysaccharidosis VI. For additional details regarding authorization for this drug, see the "Enzyme Replacement Drugs" topic in this manual section.

Dosage

The recommended dose is 1 mg/kg once a week.

Billing

HCPCS code J1458 (injection, galsulfase, 1 mg).

Idursulfase

Hunter syndrome (Mucopolysaccharidosis II, MPS II) is an X-linked recessive disease caused by insufficient levels of the lysosomal enzyme iduronate-2-sulfatase. This enzyme cleaves the terminal 2-O-sulfate moieties from dermatan sulfate and heparan sulfate. Due to the missing or defective iduronate-2-sulfatase enzyme in patients with Hunter syndrome, dermatan sulfate and heparan sulfate progressively accumulate in the lysosomes of a variety of cells, leading to cellular engorgement, organomegaly, tissue destruction, and organ system dysfunction.

Indications

For use in patients with Hunter syndrome.

Authorization

The TAR must include a diagnosis of Hunter syndrome. For other TAR requirements, see “Authorizations” near the beginning of the “Enzyme Replacement Drugs” topic.

Dosage

The recommended dose is 0.5 mg/kg once a week.

Billing

HCPCS code J1743 (injection, idursulfase, 1 mg).

Imiglucerase

Gaucher disease is classically categorized into three main types (I, II and III) and is characterized by a deficiency of beta-glucocerebrosidase activity, resulting in accumulation of glucocerebroside in tissue macrophages which become engorged and are typically found in the liver, spleen, and bone marrow and occasionally in lung, kidney, and intestine. Secondary hematologic sequelae include severe anemia and thrombocytopenia in addition to the characteristic progressive hepatosplenomegaly, skeletal complications, including osteonecrosis and osteopenia with secondary pathological fractures. Imiglucerase catalyzes the hydrolysis of glucocerebroside to glucose and ceramide. In clinical trials, imiglucerase improved anemia and thrombocytopenia, reduced spleen and liver size, and decreased cachexia.

Indications

For long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions:

- Anemia
- Thrombocytopenia
- Bone disease
- Hepatomegaly or splenomegaly

Authorization

The TAR must include a diagnosis of Type 1 Gaucher disease. For other TAR requirements, see “Authorizations” near the beginning of the “Enzyme Replacement Drugs” topic.

Dosage

Recommended dosages range from 2.5 units/kg three times a week to 60 units/kg every two weeks. The dose should be individualized to each patient with a maximum allowable dose of 818 billed units per day. If necessary, a TAR may override this maximum dose with justification that the recipient weighs 300 lbs or more.

Billing

HCPCS code J1786 (injection, imiglucerase, per10 units).

## Laronidase

Mucopolysaccharidosis I (MPS I) is characterized by the deficiency of alpha-L-iduronidase, a lysosomal hydrolase which catalyzes the hydrolysis of terminal alpha-L-iduronic acid residues of dermatan sulfate and heparan sulfate. Reduced or absent alpha-L-iduronidase activity results in the accumulation of dermatan sulfate and heparan sulfate throughout the body and leads to widespread cellular, tissue, and organ dysfunction. MPS I includes Hurler, Hurler-Scheie, and Scheie syndromes that represent the spectrum of severity. The clinical phenotype covers a broad spectrum and patients with severe, intermediate, and mild features are classified as Hurler, Hurler-Scheie, and Scheie syndromes, respectively.

Indications

Laronidase is indicated for patients with Hurler and Hurler-Scheie forms of MPS I and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established.

Authorization

The TAR must include a diagnosis of either Hurler and Hurler-Scheie forms of MPS I, or the Scheie form with moderate to severe symptoms. For other TAR requirements, see "Authorizations" near the beginning of the "Enzyme Replacement Drugs" topic.

Dosage

The recommended dose is 0.58 mg/kg once a week.

Billing

HCPCS code J1931 (injection, laronidase, 0.1 mg).

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Velaglucerase Alfa

Gaucher disease is classically categorized into three main types (I, II and III) and is characterized by a deficiency of beta-glucocerebrosidase activity, resulting in accumulation of glucocerebroside in tissue macrophages that become engorged and are typically found in the liver, spleen and bone marrow and occasionally in lung, kidney and intestine. Secondary hematologic sequelae include severe anemia and thrombocytopenia in addition to the characteristic progressive hepatosplenomegaly, skeletal complications, including osteonecrosis and osteopenia with secondary pathological fractures. Velaglucerase alfa catalyzes the hydrolysis of glucocerebroside to glucose and ceramide.

Indications

For use in patients 4 years of age or older with Type I Gaucher disease.

Authorization

The TAR must include a diagnosis of Type I Gaucher disease. For other TAR requirements, see “Authorization” near the beginning of the “Enzyme Replacement Drugs” topic.

Dosage

The recommended dose is 60 units/kg every other week as a 60-minute infusion.

Billing

HCPCS code J3385 (injection, velaglucerase alfa, 100 units)

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

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<b>Epoetin Alfa</b>	<p>Epoetin alfa (EA) is a 165-amino acid erythropoiesis-stimulating glycoprotein manufactured by recombinant DNA technology. The product contains the identical amino acid sequence of isolated natural erythropoietin and stimulates erythropoiesis by the same mechanism as endogenous erythropoietin.</p>
Indications	<p>For the treatment of anemia due to:</p> <ul style="list-style-type: none"><li>• Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.</li><li>• Anti-retroviral therapy in HIV-infected patients.</li><li>• The effects of myelosuppressive chemotherapy in patients with non-myeloid malignancies and upon initiation, there is a minimum of two additional months of planned chemotherapy.</li><li>• Reduction of allogeneic RBC transfusion in patients undergoing elective, noncardiac, nonvascular surgery.</li><li>• Myelodysplastic syndromes.</li></ul>
Limitations of Usage	<p>EA has not been shown to improve quality of life, fatigue, or patient well-being.</p> <p>EA is not indicated for use:</p> <ul style="list-style-type: none"><li>• In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.</li><li>• In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.</li><li>• In patients scheduled for surgery who are willing and able to donate autologous blood.</li><li>• In patients undergoing cardiac or vascular surgery.</li><li>• As a substitute for RBC transfusions in patients who require immediate correction of anemia.</li></ul> <p>In the appropriate circumstances, EA may be self-administered.</p>

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CKD Patients on  
Dialysis

EA treatment may be initiated when the hemoglobin level is less than 10 g/dL, taking into consideration specific patient characteristics such as functional and cognitive status, life-expectancy, and other factors. If the hemoglobin level approaches or exceeds 11 g/dL, it is recommended that the dose of epoetin alfa be reduced or interrupted.

CKD Patients  
Not on Dialysis

EA treatment may be initiated when the hemoglobin level is less than 10 g/dL and the following conditions apply:

- The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and,
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

If the hemoglobin level exceeds 10 g/dL, it is recommended that the dose of epoetin alfa be reduced or interrupted.

Non-CKD Conditions

Certain non-CKD conditions may qualify patients to receive epoetin alfa therapy:

- Anti-retroviral therapy treated HIV-infected patients may receive epoetin alfa should they develop symptomatic anemia and have serum erythropoietin concentrations that are less than 500 IU/L. EA should be withheld if the hemoglobin level exceeds 12 g/dL and therapy resumed at a dose 25% below the previous dose when the hemoglobin declines to less than 11 g/dL.
- For patients with chemotherapy-associated anemia in non-myeloid malignancies, EA is recommended as a treatment option when the hemoglobin level has decreased below 10 g/dL and if there is a minimum of two additional months of planned chemotherapy.
- Patients undergoing elective noncardiac, nonvascular surgery to reduce allogeneic RBC transfusions may receive epoetin alfa if they are unwilling or unable to donate autologous blood. Patients should have perioperative hemoglobin between 10 and 13 g/dL.
- Patients with a myelodysplastic syndrome should have an erythropoietin level equal to or less than 500 IU/L and low or intermediate-1 risk International Prognostic Scoring System score (1.0 or less).

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Required ICD-9-CM Codes	<p>ICD-9-CM diagnosis codes are required on the claim form in the <i>Diagnosis or Nature of Illness or Injury</i> field (Box 21) of the <i>CMS-1500</i> form or in the <i>Diagnosis Codes</i> field (Box 66–67) of the <i>UB-04</i> form.</p> <ul style="list-style-type: none"><li>• CKD patients with anemia on dialysis require 585.6 for HCPCS codes J0886 and Q4081</li><li>• CKD patients with anemia not on dialysis require 585.1 – 585.5 or 585.9 for HCPCS code J0885</li><li>• Anti-retroviral therapy treated HIV-infected patients with symptomatic anemia requires 042 or 079.53 for HCPCS code J0885</li><li>• Chemotherapy-associated anemia in non-myeloid malignancies requires 285.3 for HCPCS code J0885</li><li>• Patients undergoing elective noncardiac, nonvascular surgery requires V07.8 for HCPCS code J0885</li><li>• Patients with a myelodysplastic syndrome require 238.72 – 238.75 for HCPCS code J0885</li></ul>
Dosage	<p>Evaluate the iron status in all patients before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia (for example, vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating epoetin alfa.</p> <p>The dose of EA varies according to the condition being treated. Please refer to appropriate medical literature for specific dosage recommendations.</p>

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Billing

The following HCPCS codes should be used when billing epoetin alfa:

<u>HCPCS Code</u>	<u>Description</u>
J0885	Injection, epoetin alfa, for non-ESRD use, 1,000 units
J0886	Injection, epoetin alfa, for ESRD on dialysis, 1,000 units
Q4081	Injection, epoetin alfa, for ESRD on dialysis, 100 units

If EA is administered by the provider the claim must include current and previous:

- EA dose
- Patient weight in kilograms
- Hemoglobin levels

If EA is self-administered by the patient, the claim must include:

- A statement that the drug was provided to the recipient for self-administration
- The date and quantity of drug given to the recipient
- EA doses, hemoglobin levels and patient weight in kilograms for the previous three months

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

If EA is administered outside of the general guidelines above or dosage is more than 90,000 units per week, documentation must be submitted in order to establish medical necessity.

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<b>Etonogestrel Implant</b>	Refer to the <i>Family Planning</i> section in the appropriate Part 2 manual for billing instructions for etonogestrel contraceptive implant systems (HCPCS code J7307).
<b>Ferric Carboxymaltose</b>	Ferric carboxymaltose is a colloidal iron hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.
Indication	For the treatment of iron deficiency anemia in adult patients who have any of the following: <ul style="list-style-type: none"><li>• Intolerance to oral iron</li><li>• Had unsatisfactory response to oral iron</li><li>• Non-dialysis dependent chronic kidney disease</li></ul>
Dosage	The recommended dosage: <ul style="list-style-type: none"><li>• For patients weighing 50 kg or more: 750 mg in two doses separated by at least seven days for a cumulative dose of 1,500 mg per course</li><li>• For patients weighing less than 50 kg: two doses separated by at least seven days with each dose administered as 15 mg/kg body weight</li></ul>
Billing	HCPCS code Q9970 (injection, ferric carboxymaltose, 1 mg).

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**Ferumoxytol**

Ferumoxytol is used for the treatment of iron deficiency anemia in patients 18 years of age and older with chronic kidney disease.

**Dosage**

The maximum dosage is 510 mg.

**Required Codes**

Claims for both Q0138 and Q0139 require two ICD-9-CM codes as follows:

Q0138 requires one ICD-9-CM code from each box:

<u>First ICD-9-CM Code</u>	<u>Second ICD-9-CM Code</u>
280.0	585.1
280.1	585.2
280.9	585.3
	585.4
	585.5

Q0139 requires one ICD-9-CM code from each box:

<u>First ICD-9-CM Code</u>	<u>Second ICD-9-CM Code</u>
280.0	585.6
280.1	
280.9	

Billing

The following HCPCS codes are used to bill ferumoxytol:

<u>HCPCS Code</u>	<u>Description</u>
Q0138	Ferumoxytol (Feraheme), Non-ESRD, 1 mg One unit = 1 mg Treatment of iron deficiency anemia in adults <u>without</u> chronic kidney disease.
Q0139	Ferumoxytol (Feraheme), ESRD, 1 mg One unit = 1 mg Treatment of iron deficiency anemia in adults <u>with</u> chronic kidney disease.

Codes Q0138 and Q0139 cannot be reported on the same claim.  
Claims submitted with only one ICD-9-CM code will be denied.

Claims submitted with either code Q0138 and Q0139 must include the statement "the patient has failed oral iron therapy and/or is intolerant of oral iron therapy" in order to be reimbursable. The statement should be written in the *Remarks* field (Box 80 on the *UB-04*) or in the *Additional Claim Information* field (Box 19 on the *CMS-1500*).

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<b>Filgrastim</b>	Filgrastim is a Medi-Cal benefit when used for patients with severe neutropenia.
Dosage	The specific dosage of filgrastim is variable depending on which condition or disease is being treated.
Required Codes	Filgrastim is reimbursable only with one of the following ICD-9-CM codes: 205.10 – 205.12            238.72 238.75                        288.03 V07.8                         V58.11 V66.2
Billing	HCPCS code J1442 (injection, filgrastim [G-CSF], 1 mcg).  When billing for more than 1,200 mcg, providers must document in the <i>Remarks</i> field (Box 80)/ <i>Additional Claim Information</i> field (Box 19) on the claim or on an attachment that the patient weighs more than 100 kg.
<b>Fomepizole</b>	Fomepizole, 15 mg, is billed with HCPCS injection code J1451. Reimbursement is allowed up to a maximum of 140 units.
<b>Fosaprepitant</b>	Fosaprepitant injection, 1 mg (HCPCS code J1453) has a maximum daily dosage of 150 mg. It is reimbursable when administered in combination with other antiemetic agents and is indicated for the following: <ul style="list-style-type: none"><li>• Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin</li><li>• Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy</li></ul>

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<b>Galsulfase</b>	For detailed billing policy information about galsulfase, refer to the “Enzyme Replacement Drugs” topic in this manual section.
<b>Glucarpidase</b>	Glucarpidase is a carboxypeptidase produced by recombinant DNA technology in genetically modified <i>Escherichia coli</i> . 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 <i>Treatment Authorization Request (TAR)</i> 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).

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<b>Golimumab (Intravenous)</b>	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 methotrexate, is indicated for adult patients 18 years of age and older with moderate to severely active RA.
Authorization	An approved <i>Treatment Authorization Request (TAR)</i> 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 = the entire dose administered

<b>Goserelin</b>	<p>Goserelin is reimbursable for the treatment of endometriosis, advanced carcinoma of the prostate, and for the palliative use in women with advanced breast cancer.</p> <p>Goserelin 3.6 mg (HCPCS code J9202) may be reimbursed once per month when billed in conjunction with one of the following ICD-9-CM diagnosis codes: 174.0 – 174.9, 185 or 617.0 – 617.9.</p>
Dosage	<p>The maximum dosage is 10.8 mg every 28 days.</p>
<b>Granisetron</b>	<p>Granisetron is a selective 5-hydroxytryptamine<sub>3</sub> (5-HT<sub>3</sub>) receptor antagonist with little or no affinity for other serotonin receptors.</p>
Indications	<p>Granisetron injection is indicated for:</p> <ul style="list-style-type: none"><li>• The prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer therapy.</li><li>• 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.</li></ul>

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<b>Dosage</b>	<p>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.</p> <p>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.</p>
<b>Billing</b>	<p>HCPCS code J1626 (injection, granisetron HCl, 100 mcg).</p>
<b>Growth Hormone Injections</b>	<p>For information about the use of growth hormone injections for HIV-associated wasting, see “Somatropin for HIV-Associated Wasting” in the <i>Injections: Drugs S–Z Policy</i> section in this manual.</p>
<b>Hemin</b>	<p>Hemin, 1 mg, (HCPCS code J1640) is reimbursable for females 10 years of age or older. It may be reimbursed up to a maximum of 602 mg.</p>
<b>Histrelin Acetate</b>	<p>Histrelin acetate, 10 mcg, (HCPCS injection code J1675) is reimbursable with authorization, for individuals with precocious puberty. Claims must be billed “By Report” and shall include an invoice for the kit.</p>

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<b>Histrelin Acetate Implant (Supprelin<sup>®</sup> LA)</b>	For information regarding histrelin implant, 50 mg, (HCPCS code J9226, Supprelin LA) see the <i>Non-Injectable Drugs</i> section in the appropriate Part 2 manual.
<b>Histrelin Acetate Implant (Vantas<sup>®</sup>)</b>	For information regarding histrelin implant, 50 mg, (HCPCS code J9225) see the <i>Non-Injectable Drugs</i> section in the appropriate Part 2 manual.
<b>Human Fibrinogen Concentrate</b>	Human fibrinogen concentrate is used in treatment of acute bleeding episodes in persons with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
Dosage	The usual maximum dosage is 7,000 mg (quantity of 70) per day. Claims billed for greater quantities require documentation that patient's weight exceeds 100 kg.
Required Diagnosis Code	Restricted to ICD-9-CM diagnosis code 286.3.
Billing	HCPCS code J7178 (injection, human fibrinogen concentrate, 1 mg) One unit = 1 mg

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**Hyaluranon (Gel-One)**

Hyaluranon (Gel-One) for intra-articular injection is reimbursable for treatment of the knees. Authorization is required and documentation must be submitted with the *Treatment Authorization Request* (TAR) that satisfies all of the following conditions:

- Painful osteoarthritis of one or both knees
- Inadequate response to conservative nonpharmacologic therapy
- Inadequate response to analgesics (for example, acetaminophen) and non-steroidal anti-inflammatory drugs

Dosage

The usual dose is 3 ml into the affected knee.

Billing

HCPCS code J7326 (hyaluranon or derivative, Gel-One, for intra-articular injection, per dose). Claims must be billed "By Report."

**Hyaluronan (Orthovisc)  
High Molecular Weight**

High molecular weight hyaluronan (Orthovisc) for intra-articular injection is reimbursable for treatment of the knees. Authorization is required and documentation must be submitted with the TAR that satisfies all of the following conditions:

- Painful osteoarthritis of one or both knees
- Inadequate response to conservative nonpharmacologic therapy
- Inadequate response to analgesics (for example, acetaminophen) and non-steroidal anti-inflammatory drugs

Dosage

The usual dose is 2 ml of high molecular weight hyaluronan (Orthovisc) into the affected knee at weekly intervals for three or four weeks for a total of three or four injections per affected knee.

Billing

HCPCS code J7324 (hyaluranon or derivative, Orthovisc, for intra-articular injection, per dose).

**Hydroxyprogesterone  
Caproate**

Policy information about hydroxyprogesterone caproate, billed with HCPCS code J1725 (injection, hydroxyprogesterone caproate, 1 mg) or J3490 (unclassified drug), if billing for a compounded version, is located under “Preventing Preterm Births: Hydroxyprogesterone Caproate” in the *Pregnancy: Early Care and Diagnostic Services* section of the appropriate Part 2 manual.

**Hylan G-F 20**

Hylan G-F 20 for intra-articular injection is reimbursable for treatment of the knees. Authorization is required and documentation must be submitted with the *Treatment Authorization Request (TAR)* that satisfies all of the following conditions:

- Painful osteoarthritis of one or both knees
- Inadequate response to conservative nonpharmacologic therapy
- Inadequate response to analgesics (for example, acetaminophen) and non-steroidal anti-inflammatory drugs

The TAR should state which form of Hylan G-F 20 the patient will receive, either Synvisc or Synvisc-One.

**Dosage**

Hylan G-F 20 (Synvisc): The usual dose is 16 mg into the affected knee at weekly intervals for three weeks for a total of three injections per affected knee.

Hylan G-F 20 (Synvisc-One): The usual dose is 48 mg into the affected knee. Synvisc-One combines three doses of Synvisc into a single syringe.

Providers may administer more than 48 units of Hylan G-F 20 (Synvisc-One) per day if bilateral knee injections are needed on the same day.

**Billing**

HCPCS code J7325 Hyaluranon or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg

When billing for Synvisc or Synvisc-One, one billing unit is equivalent to 1 mg.