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.

**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-10-CM diagnosis code D84.1.

**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 (Soliris®)**

Soliris is a monoclonal antibody that inhibits terminal complement activation. It is used for paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG), and anti-aquaporin-4 antibody positive neuromyelitis optica spectrum disorder (NMOSD). It is associated with an increased risk of meningococcal infections.

**Indications**

All FDA-approved indications

**Dosage**

FDA-approved dosages

**TAR Requirement**

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

**TAR Criteria**

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

- Must be prescribed for FDA-approved indications and dosages
- Prescriber must be enrolled in the Soliris REMS program
- Vaccination against Neisseria meningitides at least two weeks prior to initiation (unless Soliris [eculizumab] treatment cannot be delayed), and
- Patient must have one of the following diagnoses:
  - A diagnosis of Paroxysmal nocturnal hemoglobinuria (PNH)
  - **Documented baseline value for serum lactate dehydrogenase (LDH)**
  - **Patient must be 18 years of age or older**
  - **Patient is not on another terminal complement inhibitor such as Ultomiris (ravulizumab-cwvz)**
- A diagnosis of Atypical hemolytic uremic syndrome (aHUS)
  ❖ Documented baseline value for serum lactate dehydrogenase (LDH)
  ❖ Patient is 2 months of age or older and has a weight of at least five kilograms
  ❖ Patient does not have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
  ❖ Patient is not on another terminal complement inhibitor such as Ultomiris (ravulizumab-cwvz)
- A diagnosis of generalized Myasthenia Gravis (gMG)
  ❖ Positive serologic test for anti-acetylcholine antibodies
  ❖ Patient must be 18 years of age or older
  ❖ Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
  ❖ Documented baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 6
  ❖ Patient has had an inadequate treatment response, intolerance or contraindication to two or more immunosuppressants such as azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, methotrexate, etc.
  ❖ Patient has had an inadequate treatment response, intolerance, or contraindication to chronic IVIG therapy
- A diagnosis of Neuromyelitis optica spectrum disorder (NMOSD)
  ❖ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies
  ❖ Patient must be 18 years of age or older

**REMS Program**

Eculizumab is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) due to the increased risk of infection and death from the meningococcal disease after administration of eculizumab. Prescribers must enroll in the Soliris REMS program to ensure that patients are counseled about the risk of meningococcal infection and receive appropriate vaccination(s) and/or drug prophylaxis prior to receiving eculizumab. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1888-765-4747) or at www.solirisrems.com.

Initial authorization is for six months
Reauthorization
The patient must have a significant clinical response as evidenced by:

- Paroxysmal nocturnal hemoglobinuria (PNH)
  - Documentation of a reduction in serum LDH from pretreatment baseline
- Atypical hemolytic uremic syndrome (aHUS)
  - Documentation of a reduction in serum LDH from pretreatment baseline
- Myasthenia Gravis (gMG)
  - Documentation of reduction of (MG-ADL) total score from baseline
- Neuromyelitis optica spectrum disorder (NMOSD)
  - Patient has had fewer relapses while on Soliris therapy

Reauthorization is for 12 months

Age
Must be 2 months or older for aHUS diagnosis
Must be 18 years of age or older for PNH, gMG or NMOSD diagnosis

Suggested Codes
ICD-10-CM diagnosis codes D59.3, D59.5, G70.00, G36.0

Billing
HCPCS code J1300 (injection, eculizumab, 10 mg)

Prescribing Restrictions
Frequency of billing = 900 mg/90 units weekly for the first four weeks, followed by 1,200 mg/120 units for the fifth dose one week later, then 1200 mg /120 units every two weeks thereafter
Maximum billing unit(s) = 1,200 mg = 120 units
Edaravone
Edaravone is a free-radical scavenger in solution for intravenous (IV) administration.

Indications
Edaravone is reimbursable for the treatment of amyotrophic lateral sclerosis (ALS). The mechanism of therapeutic action is unknown; however, edaravone is a free-radical scavenger that may reduce oxidative stress of motor neurons, which has been implicated in the pathogenesis of ALS. In randomized controlled trials, edaravone has been found to slow functional deterioration in some ALS patients.

Dosage
Edaravone is administered by IV infusion as follows:

- Initial treatment cycle: 60 mg IV given daily for 14 days of a 28-day treatment cycle on an intermittent schedule (14 days on and 14 days off).
- Subsequent treatment cycles: 60 mg IV given daily for 10 days out of a 14-day period of a 28-day treatment cycle on an intermittent schedule (14 days on and 14 days off).

Age
18 years and older

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.
- The patient has been diagnosed with definite or probable ALS based on the El Escorial/Airlie House revised criteria or Awaji criteria.
- The physician’s legible, complete, and signed treatment plan/order for edaravone.

For continued authorization, the TAR should include clinical documentation that edaravone use has slowed the progression of ALS, and the patient’s overall function has improved or is superior relative to that projected for the natural course of ALS.
Required Codes
The following ICD-10-CM diagnosis code is required for reimbursement:

- G12.21 (Amyotrophic lateral sclerosis)

Billing
HCPCS code J1301 (injection, edaravone, 1 mg)
One (1) unit of J1301 = 1 mg of edaravone injection solution

**Emicizumab-kxwh**
Emicizumab-kxwh is a bispecific factor IXa-directed and factor X-directed antibody solution for subcutaneous (SQ) administration.

Indications
Emicizumab-kxwh is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

Age
All ages

Dosage
The recommended dose is a 3 mg/kg SQ injection administered once weekly for four weeks, followed by a 1.5 mg/kg SQ injection administered once weekly thereafter.
Authorization

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

- The TAR must include clinical documentation that demonstrates the following criteria:
  - The service is medically necessary.
  - The patient has a documented diagnosis of congenital factor VIII deficiency (hemophilia A).
  - The patient has developed high-titer factor VIII inhibitors (≥5 Bethesda units [Bu]).
  - The physician’s legible, complete, and signed treatment plan/order for emicizumab-kxwh as a routine prophylaxis to prevent bleeding episodes associated with hemophilia A with factor inhibitors.

Required Codes

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

- D66 (Hereditary factor VIII deficiency)
- D68.311 (Acquired hemophilia)

Billing

HCPCS code J7170 (injection, emicizumab-kxwh, 0.5 mg)
One (1) unit of J7170 = 0.5 mg of emicizumab-kxwh solution
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
- Cerliponase Alfa
- Elosulfase Alfa
- Galsulfase
- Idursulfase
- Imiglucerase
- Laronidase
- Velaglucerase Alfa
- Vestronidase Alfa-vjbk

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 National Drug Code (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 TAR Processing Center, 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 TAR Processing Center.

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 patient 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

Pompe disease is an inherited disorder of glycogen metabolism caused by the absence or marked deficiency of the enzyme lysosomal acid maltase (alpha 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

Alglucosidase alfa (Lumizyme®) is used for treatment of all patients with Pompe disease.

- Myozyme® is used for treatment of patients 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, algucosidase alfa, [Lumizyme], 10 mg).

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

Cerliponase alfa is a hydrolytic lysosomal N-terminal tripeptidyl peptidase enzyme for central nervous system (CNS) intraventricular infusion.

Indication

Cerliponase alfa slows the loss of ambulation in symptomatic pediatric and adolescent patients with late infantile neuronal ceroid lipofuscinsosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

Neuronal ceroid lipofuscinsosis (NCL) includes a group of lysosomal storage disorders that affect the nervous system. CLN2 is an inherited autosomal recessive disorder, caused by changes in the TPP1 gene.

Symptoms of CLN2 generally develop between 2 and 4 years of life, but can present at an older age. Symptoms are progressive and may include intractable seizures, ataxia, myoclonus, vision loss, and developmental delays in speech, cognition, motor function, etc.

Age

3 years and older

Dosage

300 mg administered once every other week by a CNS intraventricular infusion pump via a surgically implanted reservoir and catheter.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

1. The service is medically necessary to treat symptomatic late infantile CLN2, also known as TPP1 deficiency.

2. Additional criteria listed under “Authorization” near the beginning of the “Enzyme Replacement Drugs” topic in this section.

3. The physician’s legible, complete, and signed treatment plan/order for cerliponase alfa.
Required Codes
The following ICD-10-CM diagnosis code is required for reimbursement:
E75.4 (Neuronal ceroid lipofuscinosis)

Billing
HCPCS code J0567 (injection, cerliponase alfa, 1 mg)
One (1) unit of J0567 = 1 mg of cerliponase alfa enzyme

**Elosulfase Alfa**

Mucopolysaccharidosis IV (A and B) is also known as Morquio syndrome. This disorder consists of two forms with similar clinical findings and autosomal inheritance. The clinical features result from accumulation of keratin sulfate (KS) and chondroitin 6 sulfate (C6S). Morquio syndrome is characterized by skeletal involvement, typically presenting as short stature at approximately one year of age. Respiratory problems often develop due to cord compression and the restrictive effects of skeletal disease. Both types of Morquio syndrome can have severe or mild forms. Mildly affected patients may survive into the seventh decade. Elosulfase alfa is intended to provide the exogenous enzyme N-acetylgalactosamine-6-sulfatase that will be taken up into the lysosomes and increase the catabolism of the glycosaminoglycans KS and C6S.

**Indications**
For use in patients with Mucopolysaccharidosis type IV A (Morquio A).

**Authorization**
The TAR must include a diagnosis of Mucopolysaccharidosis IV A. For additional details regarding authorization for this drug, see “Authorization” under the “Enzyme Replacement Drugs” topic in this manual section.

**Dosage**
The recommended dose is 2 mg/kg once a week.

**Billing**
HCPCS code J1322 (injection, elosulfase alfa, 1 mg).
Eptinezumab-jjmr injection (Vyepti™)

Eptinezumab-jjmr is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand.

Indications
All FDA-approved indications

Dosage
FDA-approved dosages

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

TAR Criteria
Vyepti will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following:
  - Episodic migraine defined as 4 to 14 headache days per month, at least four of which were migraine days during the previous three-month period; or
  - Chronic migraine defined as 15 to 26 headache days per month, at least eight of which were migraine days for over three months
- Patient must have tried and failed or is intolerant to or has contraindication to at least one drug from two oral classes used for migraine prophylaxis, including antiepileptic medications, beta-blockers, calcium channel blockers or antidepressants
- Must not be taken in combination with any other monoclonal antibody targeting the CGRP pathway, such as Ajovy (fremanezumab), Emgality (galcanezumab), Aimovig (erenumab), Nurtec ODT (rimegepant) and Ubrelvy (ubrogepant).

Initial authorization is for six months
Continued therapy:
- Patient continues to meet initial approval criteria
- Patient has experienced a positive clinical response to therapy as demonstrated by a reduction in headache frequency and/or severity

Reauthorization is for twelve months

Age Limits
Must be 18 years of age or older

Billing
HCPCS code «J3032» (injection, eptinezumab-jjmr, 1 mg)

Prescribing Restrictions
Frequency of billing = 300 mg/300 units every three months
Maximum billing unit(s) = 300 mg/300 units

**Note:** Vyepti is available through a limited distribution network of specialty distributors and specialty pharmacies.

Vyepti is available through these authorized specialty distributors:

- ASD healthcare (hospitals)
  Phone: 800-746-6273
  Fax: 800-547-9413
  www.asdhealthcare.com/home
- Besse Medical
  (physician offices and clinics)
  Phone: 800-543-2111
  Fax: 800-543-8695
  https://www.besse.com/home
- Oncology Supply
  (physician offices and clinics)
  Fax: 800-248-8205
  www.oncologysupply.com/contact
- McKesson Plasma & Biologics
  (hospitals and alternate sites of care)
  Phone: 877-625-2566
  Fax: 888-752-7626
  connect.mckesson.com
- McKesson Specialty Care Division
  (physician offices)
  Phone: 855-477-9800
  Fax: 800-800-5673
  mscs.mckesson.com
Vyepti is available through the following specialty pharmacies:

Alliance Rx Walgreens Prime
Phone: 855-244-2555
Fax: 877-828-3939
alliancerxwp.com/referral-forms

Orsini Healthcare
Phone: 800-259-7145
Fax: 877-892-3019
orsinihealthcare.com/enrollment-forms

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 “Authorization” under 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).
Givosiran (Givlaari)

Givosiran is a double-stranded small interfering RNA that causes degradation of aminolevulinate synthase 1 (ALAS1) 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 (ALA) and porphobilinogen (PBG), factors associated with attacks and other disease manifestations of acute hepatic porphyria (AHP).

Indications
All FDA-approved indications

Dosage
FDA-approved dosages

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

TAR Criteria
Givosiran is considered medically appropriate if all of the following criteria are met:

- Must be for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a documented diagnosis of AHP, including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria or ALA dehydratase deficient porphyria (ADP)
- Patient has a documentation of elevated urinary or plasma PBG and/or ALA within the past year
- The patient is not anticipating having a liver transplant
- The patient does not have a history of recurrent pancreatitis
- Documentation of a minimum of two porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous hemin administration in the previous six months

Initial authorization is for 12 months
Reauthorization

- Patient continues to meet initial approval criteria
- 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.)
- Patient has shown a clinical response to therapy as evidenced by a reduction in the rate of porphyria attacks that required hospitalizations, urgent healthcare visits, or intravenous hemin administration

Reauthorization is for 12 months

Age Limits
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 = 2.5 mg/kg every month
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 2-0-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 additional details regarding authorization for this drug, see “Authorization” under the “Enzyme Replacement Drugs” topic in this manual section.

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 additional details regarding authorization for this drug, see “Authorization” under the “Enzyme Replacement Drugs” topic in this manual section.

**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 patient 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 additional details regarding authorization for this drug, see “Authorization” under the “Enzyme Replacement Drugs” topic in this manual section.

Dosage

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

Billing

HCPCS code J1931 (injection, laronidase, 0.1 mg).
**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 additional details regarding authorization for this drug, see “Authorization” under the “Enzyme Replacement Drugs” topic in this manual section.

**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.
Vestronidase alfa-vjbk

Vestronidase alfa-vjbk is a recombinant human lysosomal beta glucuronidase enzyme for intraventricular infusion.

Indications

Vestronidase alfa-vjbk is used to treat patients with Mucopolysaccharidosis VII (MPS VII or “Sly Syndrome”).

Mucopolysaccharidoses includes a group of inherited lysosomal storage disorders in which the body cannot properly break down mucopolysaccharides, specifically glycosaminoglycans (GAGs), long chains of sugar molecules that exist naturally in the body. MPS VII is an autosomal recessive disorder, caused by mutations in the glucuronidase beta (GUSB) gene. This gene defect causes a deficiency of β-glucuronidase, an enzyme required for the body’s normal metabolism of GAGs. Without β-glucuronidase, GAGs abnormally accumulate within the lysosomes of body cells and eventually cause tissue and organ dysfunction.

Symptoms of MPS VII are progressive and variable. Prominent features include macrocephaly, hydrocephalus, musculoskeletal abnormalities, vision and hearing loss, hepatosplenomegaly, heart and lung disease, and developmental and cognitive delays.

The effect of vestronidase alfa-vjbk on the central nervous system (CNS) manifestations of MPS VII has not been determined.

Age

All ages

Dosage

The recommended dose is 4 mg/kg administered IV every 2 weeks.

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 to treat MPS VII.
- Additional criteria listed under “Authorization” near the beginning of the “Enzyme Replacement Drugs” topic in this section.
- The physician’s legible, complete, and signed treatment plan/order for vestronidase alfa-vjbk.
Required Codes
The following ICD-10-CM diagnosis code is required for reimbursement:

- E76.29 (other mucopolysaccharidoses [including MPS VII])

Billing
HCPCS code J3397 (injection, vestronidase alfa-vjbk, 1 mg)
One (1) unit of J3397 = 1 mg of vestronidase alfa-vjbk enzyme

**Epoetin Alfa**
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.

**Indications**
For the treatment of anemia due to:

- Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.
- Anti-retroviral therapy in HIV-infected patients.
- 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.
- Reduction of allogeneic RBC transfusion in patients undergoing elective, noncardiac, nonvascular surgery.
- Myelodysplastic syndromes.
Limitations of Usage
EA has not been shown to improve quality of life, fatigue, or patient well-being.

EA is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- In patients scheduled for surgery who are willing and able to donate autologous blood.
- In patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.

In the appropriate circumstances, EA may be self-administered.

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).

Required ICD-10-CM Codes

ICD-10-CM diagnosis codes are required on the claim form in the Diagnosis or Nature of Illness or Injury field (Box 21) of the CMS-1500 form or in the Diagnosis Codes field (Box 66–67) of the UB-04 form.

- CKD patients with anemia on dialysis require N18.6 for HCPCS code Q4081
- CKD patients with anemia not on dialysis require N18.1 thru N18.5 or N18.9 for HCPCS code J0885
- Anti-retroviral therapy treated HIV-infected patients with symptomatic anemia requires B20 or B97.35 for HCPCS code J0885
- Chemotherapy-associated anemia in non-myeloid malignancies requires D64.81 for HCPCS code J0885
- Patients undergoing elective noncardiac, nonvascular surgery requires Z41.8 for HCPCS code J0885
- Patients with a myelodysplastic syndrome require D46.0 thru D46.9 for HCPCS code J0885
Dosage

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.

The dose of EA varies according to the condition being treated. Please refer to appropriate medical literature for specific dosage recommendations.

Billing

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

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0885</td>
<td>Injection, epoetin alfa, for non-ESRD use, 1,000 units</td>
</tr>
<tr>
<td>Q4081</td>
<td>Injection, epoetin alfa, for ESRD on dialysis, 100 units</td>
</tr>
</tbody>
</table>

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 patient for self-administration
- The date and quantity of drug given to the patient
- 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.
Epoetin alfa-epbx

Epoetin alfa-epbx is a erythropoiesis-stimulating glycoprotein solution for intravenous (IV) or subcutaneous (SQ) injection. Epoetin alfa-epbx is biosimilar to epoetin alfa.

Indications

Epoetin alfa-epbx is indicated for treatment of anemia due to the following:

- Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis.
- The effect of zidovudine administered at ≤4,200 mg/week in patients with HIV infection with endogenous serum erythropoietin levels of ≤500 mUnits/mL.
- The effect of concomitant myelosuppressive chemotherapy in patients with non-myeloid malignancies and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Epoetin alfa-epbx is indicated to reduce the need for allogeneic red blood cell (RBC) transfusions in patients with perioperative hemoglobin levels between 10 and 13 g/dL who are at high risk for perioperative blood loss from elective, non-cardiac, nonvascular surgery.

Epoetin alfa-epbx is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
- In patients scheduled for surgery who are willing to donate autologous blood.
- In patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Age

All ages

Dosage

The recommended dose of epoetin alfa-epbx depends on the treatment indication and the patient’s age, weight, pre- and post-treatment hemoglobin levels, and response to therapy.
Authorization
No Treatment Authorization Request (TAR) is generally required for reimbursement.

Required Codes
For HCPCS code Q5105, ICD-10-CM diagnosis code D63.1 (Anemia in chronic kidney disease) is required for reimbursement.

For HCPCS code Q5106, one of the following ICD-10-CM diagnosis codes is required for reimbursement:

- B20 (Human immunodeficiency virus [HIV] disease)
- B97.35 (Human immunodeficiency virus type 2 [HIV 2] as the cause of diseases classified elsewhere)
- D46.0 thru D46.9 (Myelodysplastic syndromes)
- D61.1 (Drug-induced aplastic anemia)
- D61.810 (Antineoplastic chemotherapy induced pancytopenia)
- D61.811 (Other drug-induced pancytopenia)
- D63.0 (Anemia in neoplastic disease)
- D63.8 (Anemia in other chronic diseases classified elsewhere)
- D64.81 (Anemia due to antineoplastic chemotherapy)
- Y83.0 thru Y83.9 (Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient or of later complication, without mention of misadventure at the time of the procedure)

Billing
HCPCS code Q5105 (injection, epoetin alfa, biosimilar [Retacrit] [for ESRD on dialysis], 100 units)
One (1) unit of Q5105 = 100 units of epoetin alfa-epbx

HCPCS code Q5106 (injection, epoetin alfa, biosimilar [Retacrit] [for non-ESRD use], 1000 units)
One (1) unit of Q5106 = 1000 units of epoetin alfa-epbx
**Epoetin beta**

Methoxy polyethylene glycol-epoetin beta is an erythropoiesis-stimulating agent (ESA) in solution for intravenous (IV) or subcutaneous (SQ) administration.

**Indications**

Methoxy polyethylene glycol-epoetin beta is reimbursable for the treatment of anemia associated with chronic kidney disease.

**Age**

5 years and older

**Dosage**

For adult patients with chronic kidney disease:

- Initial treatment: 0.6 mcg/kg body weight administered by IV or SQ injection once every two weeks.
- Conversion from another ESA to methoxy polyethylene glycol-epoetin beta is based on the total weekly ESA dose at the time of conversion.

For pediatric patients with chronic kidney disease:

- Conversion from another ESA to methoxy polyethylene glycol-epoetin beta is based on the total weekly ESA dose at the time of conversion.

**Authorization**

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

Methoxy polyethylene glycol-epoetin beta is not indicated or recommended for the following:

- Anemia due to cancer chemotherapy.
- The immediate correction of anemia as a substitute for red blood cell (RBC) transfusions.

Methoxy polyethylene glycol-epoetin beta is contraindicated in patients with the following:

- Uncontrolled hypertension.
- Pure red cell aplasia (PRCA) that begins after treatment with methoxy polyethylene glycol-epoetin beta or other erythropoietin protein drugs.
- History of serious or severe allergic reactions to methoxy polyethylene glycol-epoetin beta.
Methoxy polyethylene glycol-epoetin has not been shown to improve quality of life, fatigue or patient well-being.

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary to treat anemia associated with chronic kidney disease.
- Prior to the initiation of ESA therapy, the patient’s hemoglobin (Hgb) level is less than 10 g/dl and iron status reveals:
  - A transferrin saturation of at least 20 percent if the patient is an adult or at least 16 percent if the patient is a child, or
  - A ferritin level of at least 80 ng/dl, or
  - Bone marrow analysis demonstrates adequate iron stores.
- If the patient has hypertension, the patient’s blood pressure is adequately controlled before the initiation and for the duration of ESA therapy.
- For continued methoxy polyethylene glycol-epoetin beta therapy or conversion from another ESA, the goal is to maintain a Hgb level between 10 and 11 g/dl.
- The physician’s legible, complete and signed written treatment plan and order for methoxy polyethylene glycol-epoetin beta.

Required Codes
The following ICD-10-CM diagnosis code must be included for reimbursement:
N18.6 (End stage renal disease)

Billing
HCPCS code J0887 (injection, epoetin beta, 1 microgram, [for ESRD on dialysis])
One (1) unit of J0887 = 1 mcg of epoetin beta
Eravacycline (Xerava)

Eravacycline is a fluorocycline antibacterial within the tetracycline class of antibacterial drugs. Eravacycline disrupts bacterial protein synthesis by binding to the 30S ribosomal subunit thus preventing the incorporation of amino acid residues into elongating peptide chains.

Indications
All FDA-approved indications

Dosage
FDA-approved dosages

TAR Requirement
An approved Treatment Authorization Request (TAR) is required for reimbursement. The TAR must meet the following criteria for approval:

- FDA approved indications and dosages
- Must be 18 years of age or older
- Must show documentation for a diagnosis of complicated intra-abdominal infections (cIAIs) caused by one of the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Klebsiella oxytoca, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Streptococcus anginosus group, Clostridium perfringens, Bacteroides species and Parabacteroides distasonis, and
- Must show documentation of culture and sensitivity tests showing that the infection is not susceptible to the formulary alternatives, or documentation of previous intolerance or contraindication to all formulary alternatives with shown susceptibility on the culture and sensitivity tests, or
- Documentation showing that treatment was initiated during a recent hospitalization or other acute care treatment
- May be authorized for a maximum of 14 days
Age Limits
Must be 18 years of age or older

Billing
HCPCS code J0122 (injection, eravacycline, 1 mg)

Prescribing Restrictions
Frequency of billing = Every 14 days
Maximum billing units = 6,364 mg = 6,364 units

Ertapenem
Ertapenem inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins; which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Indications
All FDA-approved indications.

Dosage
FDA approved dosages.

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

TAR Criteria
Ertapenem is considered medically necessary when all of the following criteria are met:
- Must be used for FDA-approved indications and dosages
- Patient must be diagnosed with one of the following moderate to severe infections caused by susceptible bacteria:
  - Complicated intra-abdominal infections.
  - Complicated skin and skin structure infections, including diabetic foot infections without osteomyelitis.
  - Community-acquired pneumonia.

Part 2 – Injections: Drugs E-H Policy
- «Complicated urinary tract infections including pyelonephritis.
- Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynecologic infections

- Must show documentation for justification of failure to use formulary alternatives such as Beta-lactams (e.g., ceftriaxone, Augmentin), fluoroquinolones (e.g., ciprofloxacin), vancomycin, etc., or previous intolerance, allergy or contraindication to all formulary alternatives or that selection is based on local epidemiology and susceptibility patterns; or

- Ertapenem is being used for the prophylaxis of surgical site infection following elective colorectal surgery.

Billing
HCPCS code J1335 (Injection, ertapenem sodium, 500 mg).

Prescribing Restrictions
Frequency of billing = 1 gram/2 units daily for up to 14 days
Maximum billing unit(s) = 1 gram/2 units

Etelcalcetide
Etelcalcetide (Parsabiv™) is a synthetic peptide that functions as an allosteric activator of the calcium-sensing receptor (CaSR) in the parathyroid gland.

Etelcalcetide specifically binds to and activates the CaSR, which reduces parathyroid hormone (PTH) secretion from the chief cells of the parathyroid gland, which enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases PTH secretion. The reduction in PTH is associated with a concomitant decrease in serum calcium and phosphate levels.

Indications
Etelcalcetide indicated for the treatment of secondary hyperparathyroidism (HPT) in patients 18 years of age or older with chronic kidney disease (CKD) on hemodialysis.

Authorization
A TAR is required for reimbursement. Documentation of secondary HPT in patients with CKD on hemodialysis.

Required Codes
ICD-10-CM diagnosis code N25.81 is required for every claim, as well as any of the following ICD-10-CM diagnosis codes: N18.11 thru N18.6, N18.9 and D63.1.
Dosage
The recommended starting dose is 5 mg administered by IV bolus injection three times per week at the end of the hemodialysis treatment. Dose may be increased in 2.5 mg or 5 mg increments no more frequently than every four weeks. Etelcalcetide maintenance dosage should be individualized and determined by titration based on PTH and corrected serum calcium response, with a dose range between 2.5 thru 15 mg.

Billing
HCPCS code J0606 (injection, etelcalcetide, 0.1 mg)

Eteplirsen
Eteplirsen is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. Eteplirsen is designed to bind to exon 51 of dystrophin pre-mRNA, resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 51 skipping. Exon skipping is intended to allow for production of an internally truncated dystrophin protein.

Indications
Eteplirsen is indicated for the treatment of DMD in patients 2 years of age or older who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51™.

Dosage
The recommended dosage is 30 milligrams per kilogram of body weight once weekly. Administer as an intravenous infusion over 35 to 60 minutes. Dilution required prior to administration.

Dosage forms and strengths:
- 100 mg/2 ml (50 mg/ml) in single-dose vial
- 500 mg/10 ml (50 mg/ml) in single-dose vial

Required Codes
ICD-10-CM diagnosis code G71.0

Billing
HCPCS code J1428 (injection, eteplirsen, 10 mg).


**Etonogestrel Implant**

Refer to the *Family Planning* section in the appropriate Part 2 manual for billing instructions for etonogestrel contraceptive implant systems (HCPCS code J7307).

**Ferric Carboxymaltose**

Ferric carboxymaltose is a colloidal iron hydroxide in complex with carboxymaltose, a carbohydrate polymer that releases iron.

**Indications**

For the treatment of iron deficiency anemia in patients 18 years of age and older who have any of the following:

- Intolerance to oral iron
- Had unsatisfactory response to oral iron
- Non-dialysis dependent chronic kidney disease

**Dosage**

The recommended dosage:

- For patients weighing 50 kg or more: 750 mg in two doses separated by at least seven days for a maximum cumulative dose not to exceed 1,500 mg per course
- 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

**Billing**

HCPCS code J1439 (injection, ferric carboxymaltose, 1 mg).

**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-10-CM codes as follows:

Q0138 requires one ICD-10-CM code from each column:

<table>
<thead>
<tr>
<th>First ICD-10-CM Code</th>
<th>Second ICD-10-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>D50.0</td>
<td>N18.1</td>
</tr>
<tr>
<td>D50.8</td>
<td>N18.2</td>
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<tr>
<td>D50.9</td>
<td>N18.3</td>
</tr>
<tr>
<td>&lt;&lt;NA&gt;&gt;</td>
<td>N18.4</td>
</tr>
<tr>
<td>&lt;&lt;NA&gt;&gt;</td>
<td>N18.5</td>
</tr>
</tbody>
</table>

Q0139 requires one ICD-10-CM code from each column:

<table>
<thead>
<tr>
<th>First ICD-10-CM Code</th>
<th>Second ICD-10-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>D50.0</td>
<td>N18.6</td>
</tr>
<tr>
<td>D50.8</td>
<td>NA&gt;&gt;</td>
</tr>
<tr>
<td>D50.9</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Billing**

The following HCPCS codes are used to bill ferumoxytol:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
</table>
| Q0138      | Ferumoxytol, Non-ESRD, 1 mg  
One unit = 1 mg  
Treatment of iron deficiency anemia in adults without chronic kidney disease |
| Q0139      | Ferumoxytol, ESRD, 1 mg  
One unit = 1 mg  
Treatment of iron deficiency anemia in adults with chronic kidney disease |

Codes Q0138 and Q0139 cannot be reported on the same claim. Claims submitted with only one ICD-10-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).

**Fibrinogen (Human)**

Fibrinogen (human) is a human fibrinogen concentrate for intravenous (IV) infusion.
Indications

Fibrinogen (human) is used to treat acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Fibrinogen (human) is not indicated for dysfibrinogenemia.

Age

12 years and older

Dosage

The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding.

- When the fibrinogen level is known, the recommended dose is calculated as follows:
  - Dose (mg/kg body weight) = \( \frac{[\text{Target fibrinogen level (mg/dL)} - (\text{minus}) \text{measured fibrinogen level (mg/dL)})]}{1.8} \) (mg/dL per mg/kg body weight)

- When the fibrinogen level is unknown, the recommended dose is of 70 mg/kg of body weight.

- If the plasma fibrinogen level is below the accepted lower limit of the target level (80 mg/dL for minor bleeding, 130 mg/dL for major bleeding), the dose is repeated until hemostasis is achieved.

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 to treat an acute bleeding episode in a patient with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
- The plasma fibrinogen levels and bleeding assessments taken and monitored during fibrinogen treatment.
- The physician’s legible, complete, and signed treatment plan/order for fibrinogen (human) concentrate (Fibryga®).

Required Codes

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

- D68.2 (Hereditary deficiency of other clotting factors [including congenital afibrinogenemia and hypofibrinogenemia])
Billing

HCPCS code J7177 (injection, human fibrinogen concentrate [Fibryga], 1 mg)
One (1) unit of J7177 = 1 mg of human fibrinogen concentrate (Fibryga)

Filgrastim

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-10-CM diagnosis codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C92.00</td>
<td>C92.90</td>
</tr>
<tr>
<td>C92.30</td>
<td>C92.A0</td>
</tr>
<tr>
<td>C92.40</td>
<td>C92.Z0</td>
</tr>
<tr>
<td>C92.50</td>
<td>D46.0 thru D46.9</td>
</tr>
<tr>
<td>C92.60</td>
<td>D70.0 thru D70.1</td>
</tr>
</tbody>
</table>

Billing

HCPCS code J1442 (injection, filgrastim [g-csf], excludes biosimilars, 1 microgram).

When billing for more than 1,200 mcg, providers must document in the Remarks field (Box 80)/Additional Claim Information field (Box 19) on the claim or on an attachment that the patient weighs more than 100 kg.
Filgrastim-sndz
Filgrastim-sndz is a leukocyte growth factor for intravenous (IV) or subcutaneous (SQ) administration. Filgrastim-sndz is biosimilar to filgrastim.

Indications
Filgrastim-sndz is used to enhance neutrophil production for the following indications:

- Non-myeloid malignancies in patients receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
- Acute myeloid leukemia (AML) in patients receiving induction or consolidation chemotherapy.
- Non-myeloid malignancies in patients receiving myeloablative chemotherapy prior to a bone marrow transplant.
- Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in patients receiving cell therapy.
- Severe chronic neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Dosage
The recommended dose of filgrastim-sndz varies depending on the treatment indication.

Age
All ages

Authorization
No Treatment Authorization Request (TAR) is generally required for reimbursement.
Required Codes
One of the following ICD-10 CM diagnosis codes is required for reimbursement:

- D70.0 (Congenital agranulocytosis)
- D70.1 (Agranulocytosis secondary to cancer chemotherapy)
- D70.4 (Cyclic neutropenia)
- D70.8 (Other neutropenia)
- D70.9 (Neutropenia, unspecified)
- Z51.11 (Encounter for antineoplastic chemotherapy)

Billing
HCPCS code Q5101 (injection, filgrastim-sndz, biosimilar, [Zarxio], 1 microgram).
One (1) unit of Q5101 = 1 microgram of filgrastim-sndz

Fomepizole
Fomepizole, 15 mg, is billed with HCPCS injection code J1451. Reimbursement is allowed up to a maximum of 140 units.

Fosaprepitant
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:

- Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy
**Fremanezumab-vfrm (Ajovy)**
Fremanezumab is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

**Indications**
All FDA-approved indications

**Dosage**
FDA-approved dosages

**TAR Requirement**
An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that includes the following:
- Patient ≥ 18 years of old and not pregnant
- Patient has had a trial of at least one drug from two oral classes used for migraine prophylaxis, including antipileptic medications, beta-blockers or antidepressants
- Patient has a diagnosis of chronic migraine

**Age Limits**
Must be 18 years of age or older

**Billing**
HCPCS code J3031 (injection, fremanezumab-vfrm, 1 mg)

**Prescribing Restrictions**
Frequency of billing = Every month
Maximum billing units = 225 mg = 225 units

**Galsulfase**
For detailed billing policy information about galsulfase, refer to the “Enzyme Replacement Drugs” topic in this manual section.
**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-acetylglicosamine.

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

**Billing**

HCPCS code J7320 (hyaluronan or derivative, genvisc 850, for intra-articular injection 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).
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 methotrexate, 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 = the entire dose administered.

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 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. Must be for FDA-approved indications and dosages
2. Patient must be 6 years of age or older
3. Patient has documented Duchenne muscular dystrophy (DMD) with dystrophin gene mutation, amenable to exon 53 skipping documented by genetic test(s).
4. Care is under the supervision and monitoring of a neurologist, or for CCS patients, a CCS-paneled neurologist or physical medicine and rehabilitation specialist at a CCS Neuromuscular Medicine Special Care Center (SCC).
5. Documentation of the following information must be provided and for CCS patients, CCS Neuromuscular Medicine SCC or neurology center has provided the following information using the Antisense Oligonucleotide Request Form:
   a) Documentation of percent forced vital capacity (FVC) ≥ 30 percent
   b) Baseline 6-minute walk test (6MWT) or explanation of why the test cannot be performed
6. Patient is on a corticosteroid or has documented reason not to be on this medication
7. Patient is ambulatory

Initial authorization is for six months

B. Reauthorization
Golodirsen shall be reauthorized for up to one year when the initial coverage criteria are met, in addition to the following:

1. Patient has not had significant decline in FVC while on the antisense oligonucleotide treatment.
2. Motor function has improved compared to pretreatment assessment as evidenced by improved score in 6MWT, Brooke Score and/or 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 percent FVC < 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 clients 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 client’s antisense oligonucleotide treatments. SCCs should submit this documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee.

I. Policy Implementation for CCS Patients

A. Submission of authorization requests for golodirsen are not included in Service Code Groupings (SCGs). SCCs should submit a separate Service Authorization Request (SAR) with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, clinical progress notes from a visit within the past 6 months, and a copy of Antisense Oligonucleotide Request Form.

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 dependent county office. The dependent county program office shall pend and submit the SAR and Antisense Oligonucleotide Request Form to the Department of Health Care Services (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 Limits

Must be 6 years of age or older
Billing
HCPCS code J1429 (injection, golodirsen, 10 mg)

Suggested ICD-10 Diagnosis Codes
G71.01

Prescribing Restrictions
Frequency of billing = 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

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.

Indications

Prevention of nausea and/or vomiting associated with the initial and repeat courses of emetogenic cancer therapy, postoperative, anesthesia.

Dosage

For the prevention of chemotherapy-induced nausea and vomiting the recommended dosage is:

- Patients (17 years of age and older) 10 mcg/kg intravenously within 30 minutes before initiation of chemotherapy.
- Pediatric patients (2 – 16 years of age) 10 mcg/kg.

For the prevention of postoperative nausea and vomiting, the recommended dosage is:

1 mg, undiluted, administered intravenously over 30 seconds, before anesthetic induction or immediately before reversal of anesthesia

For the treatment of postoperative nausea and vomiting, the recommended dosage is:

1 mg, undiluted, administered intravenously over 30 seconds.

Authorization

An approved TAR is required for reimbursement. The TAR must state that the treatment is for a patient with nausea and/or vomiting associated with cancer treatment.

Required Codes

ICD-10-CM diagnosis codes: K91.0, R11.0, R11.2, Z51.11 and Z98.890

Billing

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

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 – Z 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**

18 years and older

**Dosage**

The recommended dose is 100 mg SQ injection administered at weeks 0 and 4, and every 8 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 = 1 mg of guselkumab solution

**Hemin**

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.
Histrelin Acetate
Histrelin acetate, 10 mcg, (HCPCS injection code J1675) is reimbursable with authorization, for patients with precocious puberty. Claims must be billed “By Report” and shall include an invoice for the kit.

Histrelin Acetate Implant
For information regarding HCPCS code J9226 (histrelin acetate implant [Supprelin® LA] 50 mg) and HCPCS code J9225 (histrelin implant [Vantas®] 50 mg), see the Non-Injectable Drugs section in the appropriate Part 2 manual.

Human Fibrinogen Concentrate
Human fibrinogen concentrate is used in treatment of acute bleeding episodes in patients 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-10-CM diagnosis code D68.2.

Billing
HCPCS code J7178 (injection, human fibrinogen concentrate, not otherwise specified, 1 mg).
One unit = 1 mg
Hyaluronan
Hyaluronan for intra-articular injection is reimbursable for the treatment of osteoarthritis of the knees.

Authorization
An approved Treatment Authorization Request (TAR) is required for reimbursement. Documentation must include all of the following:

- 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

Billing
HCPCS code J7324 (hyaluronan or derivative, Orthovisc®, for intra-articular injection, per dose).
HCPCS code J7326 (hyaluronan or derivative, GelOne®, for intra-articular injection, per dose).
HCPCS code J7327 (hyaluronan or derivative, Monovisc®, for intra-articular injection, per dose).
HCPCS code J7328 (hyaluronan or derivative, Gel-Syn®, for intra-articular injection, 0.1 mg), must be billed “By Report”
Hyaluronan or Derivative Injections (Triluron Synojoynt, Durolane, Supartz Hyalgan and Euflexxa)

Hyaluronan or derivatives are injected directly into a patient’s knee for relief of pain associated with osteoarthritis. They are used for the replacement or supplementation of naturally occurring intra-articular lubricants in individuals with musculoskeletal conditions. They may work by acting as a lubricant and shock absorber in the joint, helping the knee to move smoothly, thereby lessening pain.

Indications
All FDA-approved indications

Dosage
FDA-approved dosages

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

TAR Criteria
A hyaluronan derivative intra-articular injection is considered medically appropriate if all of the following criteria are met:

• Prescribed for FDA-approved indications and dosing regimens
• Patient must be 18 years of age or older (Triluron, Hyalgan, Supartz, Euflexxa) and 21 years of age or older (Synojoynt and durolane)
• Must have documented clinical diagnosis of osteoarthritis of the knee
• Must have documented failure, inadequate response, or intolerance to at least two of the following pharmacologic therapies
  – Two oral or topical [e.g., oral non-steroidal anti-inflammatory drugs (NSAIDs), COX-2 inhibitors, or topical NSAIDS (e.g. diclofenac 1 percent gel)]
  – Acetaminophen
  – One or more trials in the last 12 months of intra-articular steroid injections unless intolerant or contraindicated
• At least one course of physical therapy for knee osteoarthritis
• No contraindications to the injections (active joint infection, bleeding disorder)
• Patient must be treated with the less expensive but clinically appropriate hyaluronan derivatives first
For treatment continuation, the following criteria must be met:
- Patient has successfully used hyaluronic acid derivatives in the same knee (there must be at least a six-month interval before approval of a repeat course)

Age Limits
Synojoynt and durolane: Must be 21 years of age or older
Triluron, Hyalgan, Supartz and Euflexxa: Must be 18 years of age or older

Billing
Durolane: HCPCS code J7318 (hyaluronan or derivative, durolane, for intra-articular injection, 1 mg)
Hyalgan/Supartz: HCPCS code J7321 (hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose)
Euflexxa: HCPCS code J7323 (hyaluronan or derivative, euflexxa, for intra-articular injection, per dose)
Synojoynt: HCPCS code J7331 (hyaluranon or derivative, synojoynt, for intra-articular injection, 1 mg)
Triluron: HCPCS code J7332 (hyaluranon or derivative, triluron, for intra-articular injection, 1 mg)

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

Prescribing Restrictions

<table>
<thead>
<tr>
<th>Product</th>
<th>Package Size</th>
<th>Dosage and Administration (per knee per 180 days)</th>
<th>Maximum billing units (per knee per 180 days)</th>
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<tbody>
<tr>
<td>Durolane</td>
<td>60 mg/ml</td>
<td>60 mg intra-articularly x 1 administration</td>
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<td>Euflexxa</td>
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<td>20 mg intra-articularly once weekly x 3 administrations</td>
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<tr>
<td>Triluron</td>
<td>20 mg/2 ml</td>
<td>20 mg intra-articularly once weekly x 3 administrations</td>
<td>60 units</td>
</tr>
</tbody>
</table>
Hydroxyprogesterone Caproate

Policy information about hydroxyprogesterone caproate can be located under “Preventing Preterm Births: Hydroxyprogesterone Caproate” in the Pregnancy: Early Care and Diagnostic Services section of the appropriate Part 2 manual. Use the following codes when billing for hydroxyprogesterone caproate:

- HCPCS code J1726 (Makena)
- HCPCS code J1729 (not otherwise specified)
- HCPCS code J3490 (unclassified drug), if billing for a compounded version

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.
Hymovis®

Hymovis is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. Hymovis is based on an ultra-pure hyaluronan, engineered using a proprietary process to increase viscosity, elasticity and residence time without chemical crosslinking. This results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in the human joint.

Indication

Hymovis 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

Hymovis is administered by intra-articular injection. A treatment cycle consists of two injections given a week apart. Strict aseptic administration technique must be followed. Inject the full 3 ml in one knee only. Do not overfill the joint. If treatment is bilateral, a separate syringe should be used for each knee.

Required Codes

CD-10-CM diagnosis codes:

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Billing

HCPCS code J7322 (hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg)
## Legend

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<td>«</td>
<td>This is a change mark symbol. It is used to indicate where on the page the</td>
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