Injections: Drugs F Policy

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

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

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).

Ferric Derisomaltose (Monoferric®)

Ferric derisomaltose is a complex of iron (III) hydroxide and derisomaltose, an iron carbohydrate oligosaccharide that releases iron. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin.

Indications

All FDA-approved indications.

Dosages

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1437 (injection, ferric derisomaltose, 10 mg).

Suggested ICD-10-CM Diagnosis Codes

Primary Diagnosis Codes:

D50.0, D50.1, D50.8, D50.9, D63.0, D63.1, D63.8, D64.81

Secondary Diagnosis Codes:

K50.0 thru K50.919, K51.0 thru K51.919, K90.0, K90.4, K90.9, N18.1 thru N18.4

Prescribing Restrictions

Frequency of billing equals 1,000 mg/100 units for one dose. May repeat dose if iron deficiency anemia reoccurs.

Maximum billing unit(s) equals 1,000 mg/100 units.

Ferumoxytol (Feraheme®)

Ferumoxytol consists of a superparamagnetic iron oxide that is coated with a carbohydrate shell, which helps to isolate the bioactive iron from plasma components until the iron-carbohydrate complex enters the reticuloendothelial system macrophages of the liver, spleen and bone marrow. The iron is released from the iron-carbohydrate complex within vesicles in the macrophages. Iron then either enters the intracellular storage iron pool (for example, ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin.

Indications

All FDA-approved indications.

Dosages

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code Q0138 (injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg [non-ESRD use])

HCPCS code Q0139 (injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg [for ESRD on dialysis])

Suggested ICD-10 Diagnosis Codes

D50.0, D50.1, D50.8, D50.9, D63.0, D63.1, D63.8, D64.81, N18.1, N18.2, N18.4 thru N18.6, N18.9.

Prescribing Restrictions

Frequency of billing equals Initial 510 mg/510 units dose followed by a second 510 mg/510 units dose three to eight days later.

Maximum billing unit(s) equals 510 mg/510 units.

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 Limit

Must be 12 years of age 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) equals [Target fibrinogen level (mg/dL) – (minus) measured fibrinogen level (mg/dL)] divided by 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 equals 1 mg of human fibrinogen concentrate (Fibryga).

Filgrastim, Filgrastim-aafi (Nvestym™), Filgrastim-sndz (Zarxio®)

‹‹See *Chemotherapy: Drugs C Policy* in the appropriate Part 2 manual for policy pertaining to filgrastim, filgrastim-aafi and filgrastim-sndz and the corresponding procedure codes.››

‹‹Fidanacogene elaparvovec-dzkt (BEQVEZ™)

Beqvez is a gene therapy designed to introduce in the transduced cells a functional copy of the factor IX gene encoding a high-activity FIX variant (FIX-R338L, hFIX Padua). The AAVRh74var capsid is able to transduce hepatocytes, the natural site of factor IX synthesis. Single intravenous infusion of BEQVEZ results in cell transduction and increase in circulating factor IX activity in patients with hemophilia B.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Must be prescribed or in consultation with a hematologist.
- Patient is under the care of hematology/oncology or Hemophilia Treatment Center (HTC).
- Patient is 18 to 64 years of age with a confirmed diagnosis of moderate to severe Hemophilia B (less than or equal to 2 IU/dL or less than or equal 2 percent endogenous factor IX) meeting all of the following:
  - Currently use factor IX prophylaxis therapy (minimum of 50 exposure days to factor IX replacement therapy), or
  - Have current or historical life-threatening hemorrhage, or
  - Have repeated, serious spontaneous bleeding episodes, and
  - Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test.››

- ‹‹Patient does not have any of the following:
  - Prior treatment with any gene therapy for Hemophilia B
  - History of chronic infection including active hepatitis B, hepatitis C or HIV
    - ❖ Positive hepatitis B surface antigen, hepatitis B virus deoxyribonucleic acid positivity, or hepatitis C virus ribonucleic acid
    - ❖ Currently on antiviral therapy for hepatitis B or C
    - ❖ Serological evidence of HIV-1 or HIV-2 with CD4 counts less than or equal to 200/mm^3 and/or a viral load greater than 20 copies/mL
  - Signs of liver disease:
    - ❖ Ascites
    - ❖ Encephalopathy
    - ❖ Coagulopathy
    - ❖ Hypoalbuminemia (levels less than the normal limits)
    - ❖ Gastrointestinal varices
    - ❖ Jaundice
    - ❖ Cirrhosis
    - ❖ Portal hypertension
    - ❖ Splenomegaly
    - ❖ Liver fibrosis-FibroScan score greater than 8 kPa units
    - ❖ FibroTest/FibroSure greater than 0.48
    - ❖ Aspartate aminotransferase (AST)-to-Platelet ratio greater than one
    - ❖ Alanine aminotransferase (ALT), AST (aspartate aminotransferase), or alkaline phosphatase greater than two times the upper limit of normal (ULN).
    - ❖ Bilirubin greater than 1.5 times the ULN
  - Renal impairment
  - Any conditions associated with increased thromboembolic risk
  - Neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid titer greater than or equal to 1:1 as detected by an FDA-approved test. More information can be found on the List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) of the FDA website.››

  - ‹‹History of or current inhibitor to FIX (greater than or equal to 0.6 Bethesda units)
  - Participated in a gene transfer trial or in a clinical trial with an investigational drug.
- Required lab:
  - Liver function tests (ALT, AST, alkaline phosphatase, bilirubin)
  - Elastography and/or ultrasound and other laboratory assessments for liver fibrosis such as Liver fibrosis-FibroScan score, FibroTest/FibroSure or AST-to-Platelet ratio if signs of liver disease are present
  - Anti-AAVRh74var neutralizing antibodies (nAb) titer
  - Inhibitor to Factor IX
  - Hepatitis B and C, and HIV screening tests
- Patient is utilizing contraception method until three consecutive samples are negative for vector shedding or six months after receiving Beqvez.
- Plan of post Beqvez administration hepatic function (ALT and AST) and Factor IX activity monitoring once or twice weekly for at least four months and as indicated per package insert.
- Monitor patients with risk factors for hepatocellular carcinoma following Beqvez administration with regular liver ultrasound and Alpha-fetoprotein testing for five years

Authorization: Three months (one treatment in a lifetime).

Reauthorization: Never.

Age Limits

Must be 18 to 64 years of age.

Billing

HCPCS code C9172 (injection, fidanacogene elaparavovec-dzkt, per therapeutic dose).››

‹‹Required ICD-10-CM Diagnosis Code

D67

Prescribing Restriction(s)

Frequency of billing is one treatment in a lifetime.

Important Instructions for Billing

When submitting a *Treatment Authorization Request* (TAR) or Service Authorization Request Submission (SAR) and claims for Beqvez™, providers are instructed to follow these steps:

Treatment Authorization Request and Service Authorization Request Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one service line on the TAR/SAR request, and enter “4” in the Units box.

Claim Submission

1. Bill using J3590 (Unclassified biologics) per therapeutic dose.
2. Completion of Claim forms:
   - This billing methodology is restricted to hospital outpatient services and hemophilia treatment centers. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - On the 837I or *UB-04* claim form, provider must submit four claim lines to represent one service.
       - ❖ Each claim line to represent one unit.
       - ❖ Claims submitted with one or two claim lines will be denied.››

- ‹‹Provider must submit an invoice for reimbursement.
- This process will ensure that the total reimbursement paid for the four claim lines is no more than the paid price on the provider submitted invoice.
- Beqvez™ must be billed on its own with no other drug or biological.

3. Providers are advised to take the following steps to ensure Beqvez™ claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Beqvez“on the “Remarks” section of the *UB-04* claim form (Field 80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary/Gainwell Technologies
     P.O. Box 526006
     Sacramento, CA 95852-6006

   - Electronic claims may be identified by notation of ‘Beqvez’ on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for Beqvez™ shall be a once in a lifetime reimbursement under C9172 or J3590 or any other code (HCPCS, CPT®, or by NDC).
6. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and UB-04 Completion: Outpatient Services for completion of the *UB-04* form.››

Fluphenazine Hydrochloride Injection

Fluphenazine is a piperazine phenothiazine antipsychotic which blocks nonselectively postsynaptic mesolimbic dopaminergic D_2 receptors in the brain.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J2679 (injection, fluphenazine hcl, 1.25 mg).

Required ICD-10-CM Diagnosis Codes

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia)

F31.0 through F31.31 (Bipolar Disorder**)**

Prescribing Restriction(s)

Frequency of billing equals 10 mg/8 units per day.

Maximum billing unit(s) equals 10 mg/8 units.

Fomepizole

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

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 equal to or greater than 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 Limit

Must be 18 years of age or older.

Billing

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

Prescribing Restrictions

Frequency of billing equals every month.

Maximum billing units equals 225 mg equals 225 units.

Furosemide (FUROSCIX®)

Furosemide primarily inhibits the reabsorption of sodium and chloride in the proximal and distal tubules and in the loop of Henle. The high degree of diuresis is largely due to the unique site of action. The action on the distal tubule is independent of any inhibitory effect on carbonic anhydrase and aldosterone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosage.
- Patient has a diagnosis of NYHA Class II or Class III chronic heart failure.
- Patient must be 18 years of age or older.
- Patient has an active prescription for an oral diuretic, equivalent to a daily total furosemide dose of 40 to 160 mg.
- Provider attests that the patient is showing signs of volume expansion due to chronic heart failure.

- Provider must show justification for failure to use furosemide intravenous injection.
- Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by all of the following:
  - Oxygen saturation is at least 90 percent on exertion
  - Respiratory rate is less than 24 breaths per minute
  - Resting heart rate is less than 100 beats per minute
  - Systolic blood pressure is more than 100 mmHg

Authorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J1941 (Injection, furosemide (Furoscix), 20 mg)

Prescribing Restriction(s)

Maximum billing unit(s) equal 80 mg/4 units.

Legend

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

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