

Reimbursement Quick Reference

ICD-10-CM DIAGNOSIS CODING

ICD-10 Code/Code Range	Descriptor
N18.1-N18.9	Chronic Kidney Disease (CKD) Stages 1-5, End-Stage Renal Disease, CKD Unspecified
D63.1	Anemia in Chronic Kidney Disease

DRUG ADMINISTRATION CODING

CPT Code	CPT Code Descriptor
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single, or initial substance/drug (15 minutes or less)
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, separate, or sequential substance/drug (15 minutes or less)
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour (16-90 minutes)
96366	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
96367	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, separate, or sequential substance/drug (16-90 minutes)

VENOFER HCPCS CODE

HCPCS	HCPCS Descriptor
J1756	Injection, iron sucrose, 1 mg

VENOFER NATIONAL DRUG CODES (HIPAA 11-digit format)

NDC Code	Vial Size
00517-2325-10	2.5 mL Single-dose vial (50 mg) (10/pack)
00517-2340-10	5 mL Single-dose vial (100 mg) (10/pack)
00517-2340-25	5 mL Single-dose vial (100 mg) (25/pack)
00517-2340-99	5 mL Single-dose vial (100 mg) (10/pack) Premier ProRx
00517-2310-05	10 mL Single-dose vial (200 mg) (5/pack)

For Intravenous Use Only

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to Venofor.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Venofor. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. If hypersensitivity reactions or signs of intolerance occur during administration, stop Venofor immediately. Monitor patients for signs and symptoms of hypersensitivity during and after Venofor administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Venofor when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Most reactions associated with intravenous iron preparations occur within 30 minutes of the completion of the infusion.

Hypotension: Venofor may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of Venofor. Hypotension following administration of Venofor may be related to rate of administration and/or total dose delivered.

Iron Overload: Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. All adult and pediatric patients receiving Venofor require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin, and transferrin saturation). Do not administer Venofor to patients with evidence of iron overload. Transferrin saturation (TSAT) values increase rapidly after intravenous administration of iron sucrose; do not perform serum iron measurements for at least 48 hours after intravenous dosing.

ADVERSE REACTIONS

Adult Patients: The most common adverse reactions in clinical trials ($\geq 2\%$ and greater than comparator) included diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain, and peripheral edema.

Pediatric Patients: The most common adverse reactions in clinical trials ($>2\%$) were headache, respiratory tract viral infection, peritonitis, vomiting, pyrexia, dizziness, cough, nausea, arteriovenous fistula thrombosis, hypotension, and hypertension.

Post-Marketing Experience

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. In post-marketing safety studies of Venofor in 1,051 patients with hemodialysis-dependent chronic kidney disease (HDD-CKD), adverse reactions reported by $>1\%$ were cardiac failure congestive, sepsis, and dysgeusia.

- *Immune system disorders:* anaphylactic-type reactions, angioedema
- *Psychiatric disorders:* confusion

- *Nervous system disorders:* convulsions, collapse, light-headedness, loss of consciousness
- *Cardiovascular system:* bradycardia, shock, acute myocardial ischemia with or without myocardial infarction or with in-stent thrombosis in the context of a hypersensitivity reaction
- *Respiratory, thoracic, and mediastinal disorders:* bronchospasm, dyspnea
- *Musculoskeletal and connective tissue disorders:* back pain, swelling of the joints
- *Renal and urinary disorders:* chromaturia
- *General disorders and administration site conditions:* hyperhidrosis

Symptoms associated with Venofor total dosage or infusing too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. These adverse reactions have occurred up to 30 minutes after the administration of Venofor injection. Reactions have occurred following the first dose or subsequent doses of Venofor. Slowing the infusion rate may alleviate symptoms.

Injection site discoloration has been reported following extravasation. Assure stable intravenous access to avoid extravasation.

DRUG INTERACTIONS

Venofor may reduce the absorption of concomitantly administered oral iron preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy

Untreated iron deficiency anemia (IDA) in pregnancy is associated with adverse maternal outcomes such as post-partum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Venofor), which may cause fetal bradycardia, especially during the second and third trimester.

Pediatric Use

Safety and effectiveness of Venofor for iron replacement treatment in pediatric patients with dialysis-dependent or non-dialysis-dependent chronic kidney disease (CKD) have not been established.

Geriatric Use

Dose administration to an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

INDICATION AND USAGE

Venofor[®] (iron sucrose) injection, USP is indicated for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD).

For additional Safety Information, please see accompanying Full Prescribing Information.

You are encouraged to report adverse drug events to American Regent, Inc.[®] at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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