Venofer®
iron sucrose injection, USP

Reimbursement Handbook

Information current as of March 2025

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For Intravenous Use Only

INDICATION AND USAGE

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

SELECTED IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

Please see Important Safety Information on pages 14 to 15 and accompanying Full Prescribing Information.

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I. Introduction

For Reimbursement

Understanding today's complex world of healthcare reimbursement requires a good sense of direction. Even though Venofer® (iron sucrose) injection, USP has been in the marketplace since the year 2000 as a trusted iron product, the reimbursement landscape changes daily. Constant shifts in Medicare rules, payer policies, billing edits (eg, Medically Unlikely Edits), and medical coding are reasons to refer to this guide, whether you have billed for Venofer once or a hundred times.

Caring for patients with chronic kidney disease (CKD) requires that providers work closely with third-party payers to ensure that they are paid fully and fairly for medically necessary healthcare items and services. American Regent®, the manufacturer of Venofer, wants prescribing providers to better understand the complexities of reimbursement. The company has prepared this guide to assist you with common questions about Venofer and its reimbursement.

This guide provides general coverage, coding, and updated payment information about Venofer to help you better understand the policies of the Medicare program and other third-party payers. This guide may also help you avoid troublesome denials based on real-world data. The goal is to help you get paid fully and fairly for every claim.

If you need more help, American Regent's **AR Assist™ program** is available to provide assistance and to answer your payment questions. For assistance call 877-448-4766, Monday through Friday, between 8 AM and 7 PM ET.

Please see Important Safety Information on pages 14 to 15 and accompanying Full Prescribing Information.

II. Coverage

For those of you who are newer to billing, coverage refers to 2 things. First, coverage is contingent upon whether the patient's policy covers a particular aspect of care. For example, if a patient has major medical coverage without prescription coverage, self-administered (prescription) drugs probably will not be covered under that benefit. But non-self-administered ("buy-and-bill") drugs, like Venofer® (iron sucrose) injection, USP, are typically covered in a doctor's office or hospital outpatient setting under the major medical benefit, as long as certain parameters are met, as described in the Medicare Coverage section below.

The second aspect of coverage is whether a particular payer, per their own policies, will cover a particular item or service. Generally, a drug is covered if it is FDA-approved, given for the diagnoses that the FDA approved it for, and administered per the package insert, which is an outline of what the FDA approved for that drug. Added to that, the drug must be necessary and appropriate for a specific patient, which means that the patient must have the correct diagnosis and be eligible, in terms of health status, to receive the product. Both public and private payers may modify or widen this coverage by issuing policies that specify how and when they will cover a product like Venofer.

Medicare Coverage

Medicare is likely to cover Venofer and its administration when used for its FDA-approved indication and when administered per its package insert. Venofer is approved for the treatment of iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD). Under Medicare Part B (the doctor's office), it must be given incident to a provider's service. In order to meet all the general requirements for coverage under the incident-to provision, an FDA-approved drug or biologic must be: a) of a form that is not usually self-administered; b) furnished by a physician practice; and c) administered by the physician or by auxiliary personnel employed by the physician and under the physician's personal supervision.[1]

The charge, if any, for the drug or biologic must be included in the physician's bill, and the cost of the drug or biologic must represent an expense to the physician. Drugs and biologics furnished by other health professionals (nurse practitioners, physician assistants, and clinical nurse specialists with Medicare billing capability) may also meet these requirements. (See sections 190, 200, and 210 in Chapter 15 of the Medicare Benefit Policy Manual for specific instructions.)[1]

In addition, Venofer is approved for maintenance therapy in pediatric (greater than 2 years of age) hemodialysis patients with iron deficiency anemia, whether or not they are on erythropoietin-stimulating agent (ESA) therapy. Venofer is also approved for maintenance therapy in pediatric (greater than 2 years of age) non-dialysis and peritoneal-dialysis patients with iron deficiency anemia who are on ESA therapy. Patients on dialysis are covered by a separate benefit under Medicare Part A. Additionally, the Medicare rules for dialysis facilities include bundled payments. The bundled per-treatment payment includes drugs, laboratory services, supplies, and capital-related costs related to furnishing maintenance dialysis. So, Venofer may be covered but not paid for separately in dialysis facilities.[2]

Additionally, for dialysis patients, there is a National Coverage Determination by Medicare, which takes precedence over local intermediary decisions. The National Coverage Determination states: "Effective October 1, 2001, Medicare also covers iron sucrose injection as a first-line treatment for iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy."[3]

For non-dialysis chronic kidney disease (CKD) patients, Medicare Part B coverage may be determined by local carriers or Medicare Administrative Contractors (MACs), who are responsible for issuing local coverage determinations (LCDs) that detail coverage guidelines.[4] Additionally, MACs are responsible for processing Medicare claims. Prior authorization (PA) is not required under Part B. Also, Medicare coverage policies must be drafted and approved by a group of clinicians in your area called the Carrier Advisory Council (CAC). This body gives the public a voice in Medicare policy. Please see the CMS.gov website for more information.*

Commercial Payers and Medicare Advantage

Medicare Part C is called Medicare Advantage (MA) and covers approximately one-third of Medicare patients, according to a non-profit organization that tracks and analyzes Medicare data.[5] MA plans are private plans that must cover the same breadth of services that traditional Medicare does. However, MA plans behave like commercial payers and not like Medicare in terms of coverage policies and some payment methodologies. Almost all private payers these days, including MA, require prior authorization for Venofer® (iron sucrose) injection, USP.

It is important to assess/determine a patient's coverage for Venofer before administering treatment. Frequent benefit investigation (sometimes known as insurance verification) is necessary for patients with commerical insurance and once in the beginning of each year for Medicare patients. If patients do not pay premiums or they change jobs, this can impact insurance coverage. Additionally, healthcare insurance policies also have various levels of coverage and may have "caps" for reimbursement of certain drugs. These details should be ascertained for each patient before services are provided.

Commercial payers often publish policies regarding iron products like Venofer. They may have Step Edits that require that one drug is "tried" before another. You should check the applicable payer policies for Venofer when you initiate Venofer therapy and each time you infuse a patient.

Medicaid

Medicaid may also cover Venofer when it is used for its FDA-approved indication. Medicaid patient eligibility guidelines and coverage policies vary from state to state, and some states maintain mandatory review criteria for including a product as an approved drug or service. Medicaid programs may base their coverage guidelines on Medicare or commercial payers or have more restrictive coverage. Most Medicaid programs require prior authorization for Venofer.

*https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=156&ncdver=1&bc=AAAAQAAAAAAA&.

III. Coding

Proper coding of services is key to your success in terms of billing for Venofer® (iron sucrose) injection, USP given in your office or clinic. Why is coding so crucial? Codes are simply an abbreviated way of describing the appropriateness and medical necessity of treatments given in your facility. This is what codes describe, in a nutshell:

- **ICD-10-CM/diagnosis codes**
  show medical necessity of Venofer in terms of the reason for giving it
- **CPT (HCPCS Level I) codes**
  demonstrate how Venofer was given to the patient
- **HCPCS Level II codes**
  provide evidence of the type of drug and how much of it was given or wasted

More details are documented below.

A. International Classification of Disease, 10th Edition, Clinical Modification (ICD-10-CM) Diagnosis Coding for Venofer

ICD-10-CM diagnosis codes identify the patient's diagnosis and inform insurers of why a service was provided. It should be simple, but there are specifics with Venofer. First of all, there is a coding guideline that states: "Certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD-10-CM has a coding convention that requires the underlying condition be sequenced first, if applicable, followed by the manifestation."[6] On the Venofer package insert, the indication is for iron deficiency anemia in patients with chronic kidney disease. So, per coding guidelines, the chronic kidney disease is the underlying condition (etiology), and the resulting condition (manifestation) is the iron deficiency anemia. Therefore, it is very important that **2 codes are billed**—the one for CKD and the one for iron deficiency anemia.

Examples of diagnosis codes, regardless of the setting, that may support the use of Venofer in CKD patients include the following:

Code Number	Description From ICD-10-CM 2020
N18.1	Chronic kidney disease, Stage 1 OR
N18.2	Chronic kidney disease, Stage 2 (mild) OR
N18.30	Chronic kidney disease, Stage 3 unspecified OR
N18.31	Chronic kidney disease, Stage 3a OR
N18.32	Chronic kidney disease, Stage 3b OR
N18.4	Chronic kidney disease, Stage 4 (severe) OR
N18.5	Chronic kidney disease, Stage 5 OR
N18.6	End-stage renal disease OR
N18.9	Chronic kidney disease, unspecified*
D63.1	Anemia in chronic kidney disease

Venofer® (iron sucrose) injection, USP is approved for the treatment of iron deficiency anemia in adult patients with CKD. In addition, it is also approved for maintenance therapy in pediatric (greater than 2 years of age) hemodialysis patients with IDA, whether or not they are on ESA therapy. Venofer is also approved for maintenance therapy in pediatric (greater than 2 years of age) non-dialysis and peritoneal-dialysis patients with IDA who are on ESA therapy. American Regent® makes no representation that Venofer is safe and effective in other patients or that it is permissible or legal to use for other indications.

That being said, payers may use other codes **for the anemia**. Codes that we have seen in payer policies include the following:

D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified*

*This code should not be used *unless absolutely necessary*, as many payers, particularly Medicare, will reject unspecified codes for drugs. Please query the treating provider for more specific CKD information.

Please check each individual payer for specific ICD-10-CM codes that can be used on claims. Coding is an art, not a science, so payers will vary greatly on what diagnoses they will accept. Diagnoses also must be clearly and explicitly noted in the medical chart.

American Regent does not recommend the use of any particular diagnosis code in any particular situation. The above codes are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

B. Healthcare Common Procedure Coding System (HCPCS) Codes, Level I: Current Procedural Terminology (CPT) Codes[7]

CPT codes are used to bill for services provided in the physician's office and other outpatient settings. Venofer has various injection and/or infusion times for 100 mg, 200 mg, 300 mg, and 400 mg. Depending upon the dose and its infusion time, one or more of the following codes may be appropriate:

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); each additional sequential intravenous push of a new 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); additional sequential infusion of a new drug/substance, up to 1 hour (16-90 minutes)

CPT is a registered trademark of the American Medical Association.

C. HCPCS Codes, Level II: Drug Code for Venofer

HCPCS codes are used to identify most drugs and biologics. Venofer® (iron sucrose) injection, USP has been assigned the following drug-specific HCPCS code (also known as a J-code):

J1756 Injection, Iron Sucrose, 1 mg

Each 1 mg of Venofer is equivalent to one (1) service unit. When billing for quantities greater than 1 mg, indicate the total amount used as a multiple of service units on the claim form. Service units are very important and must be included on every claim. Here are some Venofer examples:

- One (1) vial (2.5 mL) or 50 mg = 50 service units
- One (1) vial (5 mL) or 100 mg = 100 service units
- One (1) vial (10 mL) or 200 mg = 200 service units

National Drug Codes (NDCs)

NDCs are becoming more prevalent in billing for drugs. Many plans now require NDCs on every claim. Payers that currently require NDCs include UnitedHealthcare and all Medicaid plans.

The NDC for Venofer (and all drugs) should be applied to the claim in a 5-4-2 format, meaning that there should be 5 digits, then 4 digits, then 2 digits on the claim, like this:

XXXXX-XXXX-XX

Sometimes, the NDC number shown on the container label does not include 11 digits. When this happens, you will have to add zeros to keep a 5-4-2 format.

Venofer is preservative-free and available as 50 mg/2.5 mL single-use vials, 100 mg/5 mL single-use vials, and 200 mg/10 mL single-use vials. The NDC numbers are:

BILLING NDC	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)

IV. Venofer® Payment in All Settings

A. Reimbursement for Drugs—General

Drugs are reimbursed based on pricing by various organizations. Drug pricing is based on several different types of cost:

- Average wholesale price (AWP)
- Wholesale acquisition cost (WAC)
- Average sales price (ASP)
- Charged-based payment (Charges)

These terms are defined below.

Average wholesale price: This amount is set by the manufacturer based on what wholesalers are paying for the drug. This methodology is rarely used by payers in the physician office setting but is still sometimes used to pay hospitals for drugs.

Wholesale acquisition cost: This is set by the manufacturer, is usually about 20% less than AWP, and is generally used to pay both physicians and hospitals before an ASP can be established. Non-safety-net (340B) hospitals and physician offices are paid WAC plus 3% for drugs by Medicare before the ASP has been established.

Average sales price: This price is updated each quarter by manufacturers to Medicare via a spreadsheet. This includes average sales by NDC. Medicare pays all drugs in the physician's office and pass-through drugs in the hospital at ASP plus 6%. Non-pass-through drugs can be paid at ASP plus 6% in the hospital outpatient setting also, but not always. See the Hospital Outpatient section for more details.

Charge-based payment: It has been estimated that about a quarter of hospital drug payments are based on a formula using hospital charges. Sometimes this formula is a percentage of what the hospital charges; other times, it is a ratio of the hospital's cost to its charges.

B. Wastage—All Drugs

Venofer is packaged in single-use vials containing 50 mg, 100 mg, or 200 mg. If less than the entire vial is administered, the remainder must be discarded. Current Center for Medicare & Medicaid Services (CMS) policy for outpatient or office-administered drugs permits billing for the entire vial even if the entire contents are not used—but only if the unused portion is discarded and it is appropriately documented.* The discarded amount is billed on a second claim line with a "JW" modifier. Note that it is not permissible to bill for two patient doses from the same vial if the drug is packaged as a single-dose vial.[8]

Commercial and Medicaid payers may accept 2-line billing with Modifier JW attached to the wastage, like Medicare does. However, many non-Medicare payers will allow hospital and office providers to incorporate the wastage into the total units billed for the drug so that the wastage and infused drug are combined.

*Visit the Center for Medicare & Medicaid Services (CMS) website at www.cms.gov, to view the most current policies for billing of unused drugs.

C. Drug Payment in the Physician's Office Setting

Medicare

Currently, the payment methodology for all separately payable drugs administered in physicians' offices under Medicare is the published Average Sales Price (ASP), which includes a 6% acquisition fee. These rates are updated quarterly by the Center for Medicare & Medicaid Services (CMS). Medicare will cover 80% of the allowable amount, while the beneficiary or their supplemental insurance covers the remaining 20%. Until 2030, there will be 2% removed from the 80% Medicare pays for sequestration so that Medicare actually pays ASP plus 4.3% for all office-administered drugs, including Venofer® (iron sucrose) injection, USP.

Private Payers

For private payers, the reimbursement methodologies vary for provider-administered drugs. Reimbursement for Venofer may be based on the ASP (most likely in the physician's office), or the average wholesale price (AWP).

Medicaid

For Medicaid, reimbursement varies by state. It is usually based on AWP or ASP but can also be a percentage of charges or based upon a state-specific fee schedule purchased from an outside source or developed internally. Before administering Venofer, be sure to check with your state Medicaid entity.

D. Drug Payment in the Hospital Outpatient Department

Medicare

Under the Hospital Outpatient Prospective Payment System (HOPPS), drugs and biologics have different payments throughout their product life cycle. Older drugs, like Venofer, that are more than 2 to 3 years after launch, receive either packaged payment or separate payment through their own Ambulatory Payment Classification (APC). The APC is a payment grouping used for hospital outpatient claims as well as ambulatory surgical center (ASC) claims.

Each APC group is assigned a preset payment amount, which is intended to cover the hospital's costs related to the item or service provided. This method of payment ONLY applies to fee-for-service Medicare beneficiaries—not those enrolled in Medicare Advantage Plans.

Some drugs, like Venofer, are packaged based upon a daily predetermined per-encounter rate that varies each calendar year. That means, if the drug's per-encounter cost is less than the predetermined threshold, the drug is packaged into the APC of the drug administration for that Venofer encounter.

Medicare groups Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes for Venofer administration into the corresponding APCs for payment and, thereby, does not pay separately for it. It becomes part of the APC payment for the administration. The following CPT codes may be used to bill for the administration of Venofer and are assigned to each corresponding APC group.

CPT Code	CPT Code Descriptor	APC	APC Group Title
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or, initial substance/drug (15 minutes or less)	APC 5693	Level 3 Drug Administration
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/ drug (15 minutes or less)	APC 5691	Level 1 Drug Administration
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour (16 to 90 minutes)	APC 5693	Level 3 Drug Administration
96366	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	APC 5691	Level 1 Drug Administration
96367	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); addtional sequential infusion of a new drug/substance, up to 1 hour (16 to 90 minutes)	APC 5692	Level 2 Drug Administration

Private Payers

Reimbursement can vary by payer and may be based on the average sales price (AWP), average wholesale price (AWS), or a negotiated rate based on charges.

Medicaid

The reimbursement for Medicaid patients varies by state and their methodology for paying hospitals. Providers should check their state's Medicaid drug reimbursement fee schedule, if one exists, or the hospital's negotiated contract rates to determine their payment.

E. Reimbursement in Dialysis Centers

Medicare

All US-citizen patients—pediatric and adult—once they go on dialysis, are covered under the Medicare End-Stage Renal Disease (ESRD) benefit, provided that eligibility requirements are met. The ESRD benefit is paid for by Medicare Part A. Section 1881(b)(14) of the Social Security Act and requires a bundled payment for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD, effective January 1, 2011. The bundled ESRD payment provides a patient-level and facility-level adjusted per-treatment (dialysis) payment to ESRD facilities for renal dialysis services provided in an outpatient or office facility or in a beneficiary's home. The bundled per-treatment payment includes drugs, like Venofer® (iron sucrose) injection, USP, laboratory services, supplies, and capital-related costs related to furnishing maintenance dialysis. So, Venofer is covered in these facilities but is not paid separately.

F. Denials for Venofer

All provider-administered ("buy-and-bill") drugs have complicated payment scenarios based on cost and various payer coverage policies. Moreover, for non-traditional Medicare payers (like Medicare Advantage plans), prior authorization is needed for Venofer® (iron sucrose) injection, USP to be paid. Denials are common and create much follow-up for providers. Venofer is no exception; however, some of its denials are unique to its indication of iron deficiency anemia in patients with chronic kidney disease. Below are the top 5 denial codes for Venofer in the buy and bill setting, an explanation as to why they may be happening and how they may be prevented.

1. **Claim Denial Code #50, Lack of Medical Necessity:** This denial code seems to imply that payers are not covering Venofer because the reasons for the administration are not covered. However, in looking at the data, most claims denied under this denial code are not coded correctly in terms of their diagnosis. The top denied ICD-10-CM diagnosis code is D50.9, "unspecified anemia." Unspecified codes for drugs are very often denied. It is important to use the most specific code that matches individual record documentation. Further, it is also vital to check all individual payer policies for coding guidance and, if they are not available, review the applicable ICD-10-CM guidelines to choose the optimal code for payment of Venofer.

2. **Claim Denial Code #16, Missing Claim Information:** This denial code is the most common denial code for all drugs. Most often, this denial is issued for a lack of or an incorrect National Drug Code (NDC). All NDCs should be in the proper format and should be reported to Medicaid, and other payers in your area that require it. Other reasons for this code include wrong provider number, lack of units of service, wrong patient numbers, and other clerical omissions. It is important for each claim to be checked to ensure that all billing information is present.

3. **Claim Denial Code #29, The Time for Claim Filing Expired:** This denial code denotes that the claim cannot be paid because the deadline for filing has expired. Medicare's billing deadline is 365 days. Other payers will vary as to their deadline, but it is important to check all payer contracts and ascertain the billing window for each one. Note that payer deadlines may be extended for natural disasters/emergencies or internal situations, such as fire and theft.

4. **Claim Denial Code #11, The Procedure Code and Diagnosis Code Do Not Match:** This denial means that the payer expects to see a different diagnosis with the Venofer Healthcare Common Procedure Coding System (HCPCS) code. Again, unspecified codes are a problem, as they are codes that do not convey the diagnosis on the Venofer package insert. Further, there are some claims for diagnoses that are not indicated for Venofer. Please verify coverage and coding guidelines prior to administration of Venofer.

5. **Claim Denial Code #197, Lack of Prior Authorization:** Almost all payers outside of traditional Medicare require prior authorization for branded drugs and biosimilars. According to the data, it is not enough to simply obtain a prior authorization. It is also important that authorization numbers are recorded if issued and that the diagnosis code that is approved is the same one that is billed. The claim must reflect exactly what was approved.

If you receive a Venofer denial and have questions about it, please call AR Assist™ at 877-448-4766, Monday through Friday, between 8 AM and 7 PM ET.

V. AR Assist™ Coverage and reimbursement assistance

AR Assist is here for you. American Regent® created AR Assist in support of our mission to help ensure that patients have access to the medications they need.

- **Benefits Verifications:** AR Assist reimbursement specialists help physicians and other providers understand payers' coverage and reimbursement policies for Venofer®, including insurance benefit verification
- **Claims Appeals:** AR Assist reimbursement specialists support providers in appealing denied claims or inadequate reimbursement for Venofer. AR Assist specialists help track claims through the process, including follow-up with payers to help navigate the complex process. If a claim is denied, our staff is here to help
- **Prior Authorization Support:** AR Assist reimbursement specialists can help physicians and providers through the process of seeking pre-certifications and pre-authorizations for Venofer. Patient information will be kept strictly confidential at all times

AR Assist is here for you

Call the hotline toll free Monday through Friday between 8 am to 7 pm ET.

877-448-4766

Access our reimbursement support services whenever you need them by using the AR Assist healthcare provider portal!

Benefits include:

- Easy and quick registration
- Convenient access 24 hours a day, 7 days a week
- All your patient information in one location and so much more!

Register today at portal.ar-assist.com

Venofer®
iron sucrose injection, USP

Patient information will be kept strictly confidential at all times. Every attempt is made to provide accurate, up-to-date information. AR Assist cannot guarantee successful reimbursement. To speak with someone at American Regent's Customer Service department, please call 800-645-1706.

Please see Important Safety Information on pages 14 to 15 and accompanying Full Prescribing Information.

Venofer®
iron sucrose injection, USP

For Intravenous Use Only

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

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 Venofer. 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 Venofer immediately. Monitor patients for signs and symptoms of hypersensitivity during and after Venofer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Venofer 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: Venofer may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of Venofer. Hypotension following administration of Venofer 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 Venofer require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin, and transferrin saturation). Do not administer Venofer 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 (≥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 Venofer 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 Venofer 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 Venofer injection. Reactions have occurred following the first dose or subsequent doses of Venofer. Slowing the infusion rate may alleviate symptoms.

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

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Untreated 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 Venofer), which may cause fetal bradycardia, especially during the second and third trimester.

Pediatric Use

Safety and effectiveness of Venofer for iron replacement treatment in pediatric patients with dialysis- dependent or non-dialysis-dependent 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

Venofer® (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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Venofer®
iron sucrose injection, USP

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REFERENCES

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Reliable. Responsive. Respected.

Venofer®
iron sucrose injection, USP

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)

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Venofer®
iron sucrose injection, USP

For Intravenous Use Only

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

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 Venofer. 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 Venofer immediately. Monitor patients for signs and symptoms of hypersensitivity during and after Venofer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Venofer 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: Venofer may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of Venofer. Hypotension following administration of Venofer 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 Venofer require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin, and transferrin saturation). Do not administer Venofer 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 (≥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 Venofer 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 Venofer 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 Venofer injection. Reactions have occurred following the first dose or subsequent doses of Venofer. Slowing the infusion rate may alleviate symptoms.

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

DRUG INTERACTIONS

Venofer 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 Venofer), which may cause fetal bradycardia, especially during the second and third trimester.

Pediatric Use

Safety and effectiveness of Venofer 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

Venofer® (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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