Venofer®
iron sucrose injection, USP

Reimbursement Guide and Patient Assistance Program

For Intravenous Use Only

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

SELECTED IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Venofer is contraindicated in patients with known hypersensitivity to Venofer.

Please see Important Safety Information on pages 22 to 23 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. The guide should 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 **VenAccess™ Reimbursement Hotline** is available to provide assistance and to answer all of your payment questions. This hotline can be reached by calling 877-4-IV-IRON (877-448-4766), Monday through Friday, between 9 AM and 8 PM ET.

Please refer to the Venofer full Prescribing Information enclosed in the pocket of this guide and the Important Safety Information on pages 22 to 23.

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, will be 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 next paragraph.

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 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 170, 180, 190, and 200 in Chapter 15 of the Medicare Benefit Policy Manual for specific instructions.)[1]

In addition, Venofer® (iron sucrose) injection, USP 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 of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy."[3]

For non-dialysis 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, carriers and 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 (link below) for more information.*

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

Commercial Payers and Medicare Advantage

Medicare Part C is called Medicare Advantage (MA) and currently covers approximately 36.5% of Medicare patients. MA plans are private plans that must cover the same breadth of services that traditional Medicare does. But, other than that, MA behaves like a commercial payer and not like Medicare in terms of coverage and payment. Almost all private payers these days, including MA, require prior authorization for branded drugs like Venofer® (iron sucrose) injection, USP. This will tell you definitively whether a commercial plan will cover Venofer for your patient.

Frequent benefit investigation (sometimes known as insurance verification) is necessary for commercial patients—particularly if they are Affordable Care Act (ACA) patients with premiums or are on employer-based insurance. If patients do not pay premiums or they change jobs, this can impact insurance coverage. Healthcare insurance policies also have various levels of coverage and may have "caps" for drugs. This needs to be ascertained for each policy.

Additionally, commercial payers often publish policies regarding iron products like Venofer. You should check the payer policies for Venofer each time you infuse a patient and each time you initiate a new course of iron treatment with Venofer. You can also verify how a policy applies to your patient at the time of prior authorization.

Medicaid

Medicaid may also cover Venofer when it is used for its FDA-approved indications. 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 in 2020 require prior authorization for branded drugs like Venofer.

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 it can get difficult 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."[5] On the Venofer package insert, the indication is for iron deficiency anemia in 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.

Please see Important Safety Information on pages 22 to 23 and accompanying Full Prescribing Information.

Examples of diagnosis codes, regardless of the setting, that may support the use of Venofer® (iron sucrose) injection, USP in CKD patients include the following:

Code Number	Description From ICD-10-CM 2020
N18.1	Chronic kidney disease, Stage I OR
N18.2	Chronic kidney disease, Stage II (mild) OR
N18.3	Chronic kidney disease, Stage III (moderate) OR
N18.14	Chronic kidney disease, Stage IV (severe) OR
N18.5	Chronic kidney disease, Stage V OR
N18.6	End stage renal disease OR
N18.9	Chronic kidney disease, unspecified*
D63.1	Anemia in chronic kidney disease

Venofer 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

CPT codes are used to bill for services provided in both the physician's office and other outpatient settings. Venofer® (iron sucrose) injection, USP has various injection and/or infusion times for the 100 mg, 200 mg, 300 mg, and 400 mg vials. Depending upon the dose and its infusion time, use the appropriate code(s) from this list:

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)
96367	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, separate or sequential substance/drug (16-90 minutes)
96366	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); each additional hour, up to 8 hours (list separately in addition to code for primary procedure) (over 30 minutes into the next hour)

†CPT is a registered trademark of the American Medical Association. All rights reserved. 2020.

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)

National Drug Codes are becoming more prevalent in billing for drugs. Many plans now require NDCs on every claim. The most prominent payers to require NDCs are 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

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:

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)

A description of these methods follows 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® (iron sucrose) injection, USP 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 CMS policy for outpatient or office-administered drugs permits billing for the entire vial even if the 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 Medicare twice for the same vial if the drug is packaged as a single-dose vial.

Commercial and Medicaid payers may accept 2-line billing with Modifier JW attached to the wastage, like Medicare does. UnitedHealthcare, since 2018, has required 2-line billing. However, many non-Medicare payers will allow hospital and office providers to incorporate the wastage into the total units for the drug so that the wastage and infused drug are combined.

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 ASP, which includes a 6% acquisition fee. These rates are updated quarterly by CMS. Medicare will cover 80% of the allowable amount, while the beneficiary or their supplemental insurance covers the remaining 20%. Until 2025, 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, like Venofer.

Private Payers

For private payers, the reimbursement methodologies vary for provider-administered drugs. Reimbursement for Venofer® (iron sucrose) injection, USP may be based on the ASP, which is most likely in the physician's office, or the AWP.

Medicaid

For Medicaid, reimbursement varies by state. It is usually based on AWP or cost 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.

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 is, 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 CPT and HCPCS codes for Venofer® (iron sucrose) injection, USP 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 for the calendar year 2020:

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); intravenous push, separate or sequential (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
96367	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, separate or sequential (16 to 90 minutes)	APC 5692	Level 2 Drug Administration
96366	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); each additional hour, up to 8 hours (list separately in addition to code for primary procedure) (over 30 minutes into the next hour)	APC 5691	Level 1 Drug Administration

Private Payers

Reimbursement can vary by payer and may be based on the ASP, AWP, 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 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

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, prior authorization is needed for all branded drugs, like Venofer® (iron sucrose) injection, USP, to be paid. Thus, 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 chronic kidney disease. A Clearinghouse database* evidences the following top 5 denial codes for Venofer in 2019, an explanation as to why these may be happening, and how these may be prevented in the buy-and-bill setting:

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. All NDCs should be in the proper format and should be reported to Medicaid, UnitedHealthcare, 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 and every one. Additionally, payer deadlines can be extended for natural disasters 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® (iron sucrose) injection, USP 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 the VenAccess™ Reimbursement Hotline at 877-4-IV-IRON (877-448-4766), Monday through Friday, between 9 AM and 8 PM ET.

*This database houses approximately 4 million Community Oncology claims per annum.

V. VenAccess™ Reimbursement Hotline: 877-4-IV-IRON

American Regent has established a toll-free hotline to help physicians and other providers understand payers' coverage and reimbursement policies for Venofer® (iron sucrose) injection, USP, and when necessary, address reimbursement issues. Specifically, on a limited basis, hotline reimbursement specialists can assist with the following:

- **Insurance verifications:** Help callers verify payer coverage and reimbursement policies for Venofer. Reimbursement specialists will determine patient benefit levels and discuss potential billing options with patient consent
- **Billing assistance:** Assist callers with filing claims and understanding the reimbursement policies for Venofer
- **Claims appeals:** Support callers in appealing denied claims or inadequate reimbursement for Venofer
- **Patient assistance:** Screen individuals without health insurance who are ineligible for public assistance for enrollment in a product replacement program.

Using the VenAccess™ Reimbursement Hotline

The hours of operation are Monday through Friday, from 9 AM to 8 PM ET. Call the hotline toll-free at 877-4-IV-IRON.

A reimbursement specialist answers most calls. There may be times when you need to leave a message that includes your name, telephone number, and a brief summary of your question or request.

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

VI. VenAccess™ Patient Assistance Program

Program Overview

American Regent created the VenAccess™ Patient Assistance Program to help improve access to Venofer® (iron sucrose) injection, USP for non-dialysis CKD patients who lack health insurance and cannot afford therapy. If a patient meets eligibility requirements, American Regent will replace the Venofer provided, free of charge, while the patient is enrolled in the Program. American Regent reserves the right to modify or cancel the Program immediately with respect to any patient, or in its entirety, at any time.

Program Eligibility

To be eligible for the Program, non-dialysis patients must completely lack health insurance and be ineligible for public insurance or financing. The patient must also be a US citizen, legal entrant in the US, or permanent resident. Proof of citizenship or legal residency may also be required. Patients must also meet income and other criteria established by American Regent.

How to Apply

Providers may apply to the Program on behalf of their patients by following these steps:

Patient or Provider

1 ENROLL

Provider submits patient application.

A hospital, physician, or infusion center may apply to the Program on behalf of its non-dialysis patients. The provider submits a patient application for each patient, which is used to determine patient eligibility. Please visit **www.Venofer.com/Patient-Assistance** to download a copy of this form.

The provider may also contact the Program at **877-4-IV-IRON** to apply by telephone. Program staff will ask the healthcare provider for the patient's insurance and financial information to determine whether the patient is likely to qualify.

(Note: All release of information is subject to patient authorization and consent.)

2 CONFIRM

Provider and patient are notified of enrollment status.

The provider and patient will receive notification by mail, fax, or email of the patient's enrollment or denial. If approved, the patient is eligible for replacement product during the enrollment period.

Provider

3 ADMINISTER

Provider requests replacement Venofer.

If the patient is approved for the Program, the provider submits a product replacement request for each patient at the end of each month. This form documents the amount of Venofer® (iron sucrose) injection, USP, provided to the patient free of charge and must be signed by a physician. The provider will receive free replacement vials approximately 30 days after the replacement request is received by the Program. Please visit **www.Venofer.com/Patient-Assistance** to download a copy of the product replacement request form.

4 REENROLL

Provider reapplies if continued assistance is required.

Providers may reapply on behalf of their patients by completing a new patient application or by calling the Program at the end of the patient's enrollment period to request reenrollment.

All Program forms should be sent to:

VenAccess™ Patient Assistance Program
c/o IV Iron Hotline
PO Box 220342
Charlotte, NC 28222
Fax: 888-354-4856

VenAccess

How to Contact the Program

Healthcare providers who would like to apply on behalf of their patients should call the VenAccess™ Patient Assistance Program.

877-4-IV-IRON
(877-448-4766)

Program staff are available Monday through Friday, between 9 AM and 8 PM ET. The address is listed above.

The completion and submission of coverage or reimbursement-related documentation are the responsibility of the patient and healthcare provider. American Regent, Inc., makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Venofer® iron sucrose injection, USP

FPO POCKET

For Intravenous Use Only

INDICATION AND USAGE

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

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

Pediatric Patients (2 Years of Age and Older)

The dosing for iron replacement treatment in pediatric patients with Peritoneal or Hemodialysis-Dependent-CKD or Non-Dialysis Dependent CKD have not been established.

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

WARNINGS AND PRECAUTIONS

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.

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.

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 (≥2%) include 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 (≥2%) are 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 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
- *Cardiac disorders:* bradycardia
- *Vascular disorders:* shock
- *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.

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.

OVERDOSAGE

No data are available regarding overdosage of Venofer in humans. Excessive dosages of Venofer may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer Venofer to patients with iron overload.

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.

Venofer®
iron sucrose injection, USP

Disclaimer

This guide is not intended to provide legal, medical, or other professional advice. This information is provided for reference only. American Regent, Inc. makes no representations or guarantees regarding the completeness or accuracy of the information in this guide and has no obligation to update this guide to reflect changes in laws that may affect reimbursement for Venofer. For assistance with legal or medical issues, you are urged to consult a qualified professional.

REFERENCES

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5. Centers for Medicare & Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting FY 2019. (October 1, 2018 – September 30, 2019). https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2019-ICD10-Coding-Guidelines-.pdf. Accessed April 8, 2020.

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Venofer® (iron sucrose) injection, USP

Reimbursement Quick Guide

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)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, separate or sequential substance/drug (16-90 minutes)
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour, up to 8 hours (List separately in addition to code for primary procedure) (Over 30 minutes into the next hour)

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)

*ICD-10-CM coding for Venofer varies greatly by payer. This coding is one alternative that adheres to ICD-10-CM Guidelines. Please check with each payer to ascertain the best coding for Venofer according to their policy.

Venofer® iron sucrose injection, USP

For Intravenous Use Only

INDICATION AND USAGE

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

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

Pediatric Patients (2 Years of Age and Older)
The dosing for iron replacement treatment in pediatric patients with Peritoneal or Hemodialysis-Dependent-CKD or Non-Dialysis Dependent CKD have not been established.

CONTRAINDICATIONS

Known hypersensitivity to Venofer.

WARNINGS AND PRECAUTIONS

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.

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.

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 (≥2%) include 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 (≥2%) are 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 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
- *Cardiac disorders:* bradycardia
- *Vascular disorders:* shock
- *Respiratory, thoracic and mediastinal disorders:* bronchospasm, dyspnea
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