Clinical Policy: Iron Sucrose (Venofer)

Reference Number: CP.PHAR.167
Effective Date: 03/16
Last Review Date: 03/17

Revision Log
Coding Implications

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of iron sucrose (Venofer®) injection.

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Venofer is **medically necessary** for members meeting the following criteria:

I. Initial Approval Criteria

A. Iron Deficiency Anemia associated with Chronic Kidney Disease (must meet all):

1. Diagnosis of iron deficiency anemia (IDA) and chronic kidney disease (CKD);
2. IDA is confirmed by either of the following:
   a. Transferrin saturation (TSAT) ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL if receiving an erythropoiesis-stimulating agent (ESA);
3. If CKD does not require hemodialysis or peritoneal dialysis, oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hemoglobin (Hgb) < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy.

Approval duration: 3 months

B. Iron Deficiency Anemia not associated with Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA confirmed by any of the following:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hb* < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased sTfR or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
2. Oral iron therapy is not optimal due to any of the following:
   a. TSAT <12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;

d. Severe or ongoing blood loss;
e. Oral iron intolerance;
f. Unable to achieve therapeutic targets with oral iron;
g. Co-existing condition that may be refractory to oral iron therapy.

Approval duration: 3 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval Criteria

A. Iron Deficiency Anemia associated with Chronic Kidney Disease (must meet all):
1. Currently receiving the medication via Centene benefit or member has previously met all initial approval criteria;
2. Either of the following measured ≥ 4 weeks after last IV iron administration;
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL if receiving an ESA.

Approval duration 3 months

B. Iron Deficiency Anemia not associated with Chronic Kidney Disease (must meet all):
1. Currently receiving the medication via Centene benefit or member has previously met all initial approval criteria;
2. Any of the following measured ≥ 4 weeks after last IV iron administration:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hgb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased sTfR or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;

Approval duration 3 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy

Background

Description/Mechanism of Action

Venofer (iron sucrose injection, USP), an iron replacement product, is an aqueous complex of poly-nuclear iron (III)-hydroxide in sucrose. Following intravenous administration, Venofer is dissociated into iron and sucrose and the iron is transported as a complex with transferrin to target cells including erythroid precursor cells. The iron in the precursor cells is incorporated into hemoglobin as the cells mature into red blood cells.

Formulations:

Intravenous solution: Venofer: 20 mg/mL (2.5 mL, 5mL, 10mL)

FDA Approved Indications:
Venofer is an iron replacement product/intravenous formulation indicated for:

- Treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hgb: hemoglobin
IDA: iron deficiency anemia
TSAT: transferrin saturation
sTfR: soluble transferring receptor

References

1. Venofer prescribing information. Shirley, NY: American Regent, Inc.; August 2015. Available from http://www.venofer.com/PDF/Venofer_PI_82015.pdf. Accessed February 20, 2017.
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4. Berns JS. Diagnosis of iron deficiency in chronic kidney disease. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
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12. Mahoney DHM. Iron deficiency in infants and young children: Screening, prevention, clinical manifestations, and diagnosis. In: UpToDate. Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
13. Mahoney DHM. Iron deficiency in infants and young children: Treatment. In: UpToDate. Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1756	Injection, iron sucrose, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	01/16	03/16
Under Section I.B, "Iron maintenance treatment in pediatric patients with CKD", the parenthetical, "see mg/kg dosing", is removed from the dosing criteria (even though dosing is weight based) as the intent of the dosing criteria is only to focus on the dose not to exceed.	10/16	
Labeled and off-labeled use, and diagnostic/follow-up tests, are edited for consistency across among ferumoxytol, ferric gluconate, iron sucrose, ferric carboxymaltose, and are made broad enough to capture use in adults, children and pregnancy. The criteria also encompass iron maintenance and replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13. Age and dose are removed/ Hypersensitivity removed as a contraindication.	02/17	03/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.