# Clinical Policy: Iron Sucrose (Venofer)

Reference Number: PA.CP.PHAR.167
Effective Date: 01/18
Last Review Date: 07/18

Revision Log
Coding Implications

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for the use of iron sucrose (Venofer®) injection.

**Policy/Criteria**
It is the policy of Pennsylvania Health and Wellness 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
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;
4. Co-existing condition that may be refractory to oral iron therapy.Dose does not exceed 500 mg elemental iron per injection.

**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.

3. At the time of the request, member does not have CKD.

**Approval duration: 3 months**

**C. Other diagnoses/indications:** Refer to PA.CP.PMN.53

**II. Continued Approval Criteria**

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

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Either of the following measured ≥ 4 weeks after last IV iron administration;
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL
3. 3. If request is for a dose increase, new dose does not exceed 500 mg elemental iron per injection.

**Approval duration 3 months**

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

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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;
3. 3. At the time of the request, member does not have CKD.

**Approval duration 3 months**

**C. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy; or

2. Refer to PA.CP.PMN.53

## 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)

## 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 October 2017.
2. KDIGO 2012 clinical practice guideline for evaluation and management of chronic kidney disease. *Kidney International Supplements.* January 2013; 3(1): 1-136.
3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
5. Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician.* 2013; 87(2): 98-104. http://www.aafp.org/afp/2013/0115/p98.pdf
6. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2017. Available at www.uptodate.com. Accessed December 2017.
7. Iron only mineral supplement formulas. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at http://www.clinicalpharmacology-ip.com. Accessed December 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 |
|---|---|---|
| Doses added. References reviewed. | 02/18 | |