VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Iron Replacement – Venofer Utilization Management Medical Policy
- Venofer® (iron sucrose intravenous infusion or slow injection – American Regent)

REVIEW DATE: 12/14/2022

OVERVIEW

Venofer, an iron replacement product, is indicated for the treatment of **iron deficiency anemia in patients with chronic kidney disease** (CKD).[1]

Dosing Information

Venofer is administered by intravenous (IV) infusion or slow injection and treatment may be repeated if iron deficiency remains persistent or recurring.[1] Dosage and dosing frequency varies depending on patient age, if there is a need for dialysis, and if needed, what type if dialysis (hemodialysis or peritoneal). The recommended maximum total course dose is 1000 mg per treatment cycle.

Guidelines

The Kidney Disease: Improving Global Outcomes guidelines for anemia in CKD (2012) make various recommendations regarding iron therapy.[2] For adults with CKD and anemia not on iron or erythroid stimulating agent (ESA) therapy, a trial of IV iron (or in non-dialysis patients with CKD, alternatively, a 1 to 3 month trial of oral iron therapy) is recommended if an increase in hemoglobin (Hb) concentration without starting ESA treatment is desired, and transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For adults with CKD on ESA therapy who are not receiving iron supplementation, a trial of IV iron (or in non-dialysis CKD patients, alternatively, a 1 to 3 month trial of oral iron therapy) is recommended if an increase in Hb concentration or a decrease in ESA dose is desired, and TSAT is ≤ 30% and ferritin is ≤ 500 ng/mL. For all pediatric patients with CKD with anemia not on iron or ESA therapy, oral iron (or IV iron in patients receiving hemodialysis) is recommended when TSAT is ≤ 20% and ferritin is ≤ 100 ng/mL. For all pediatric patients with CKD who are receiving ESA therapy but not receiving iron supplementation, it is recommended to administer oral iron (or IV iron for patients receiving hemodialysis) to maintain TSAT > 20% and ferritin > 100 ng/dL.

The National Comprehensive Cancer Network guidelines on Hematopoietic Growth Factors (version 1.2023 – December 2, 2022) discuss the management of cancer- and chemotherapy-induced anemia.[3] IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%), functional iron deficiency (ferritin = 30 to 500 ng/mL and TSAT < 50%), and possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%).

A 2017 focused update of the 2013 American College of Cardiology Foundation/American Heart Association guideline for the management of heart failure states that in patients with New York Heart Association class II or III heart failure, absolute iron deficiency (ferritin < 100 ng/mL) or functional iron deficiency (ferritin = 100 to 300 mg/mL if transferring saturation is < 20%), and with or without anemia, IV iron replacement may be reasonable to improve function status and quality of life.[4] Benefits noted with IV iron therapies included improvements in the six-minute walk test and improved functional capacity.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Venofer. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Venofer as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Venofer to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Venofer is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis**. Approve for 3 years.

2. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis**. Approve for 1 year if the medication is prescribed by or in consultation with a nephrologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

Other Uses with Supportive Evidence

3. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets one of the following (A, B, C, or D):
   - **A)** Patient meets both of the following (i and ii):
     - **i.** Patient has tried oral iron supplementation; AND
     - **ii.** According to the prescriber, oral iron supplementation was ineffective or intolerable; OR
   - **B)** Patient has a condition which, per the prescriber, will interfere with oral iron absorption (e.g., inflammatory bowel disease, Crohn's disease); OR
   - **C)** Patient is currently receiving an erythroid stimulating agent; OR
     Note: Examples of erythroid stimulating agents include an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product.
   - **D)** The medication is being requested for cancer- or chemotherapy-related anemia.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

4. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the medication is being prescribed by or in consultation with a cardiologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Venofer is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Venofer® intravenous infusion or slow injection [prescribing information]. Shirley, NY: American Regent; July 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012;2(Suppl):279-335.
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 1.2023 – December 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 9, 2022.
4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. *J Am Coll Cardiol*. 2017;70(6):776-803.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/15/2021
Annual Revision	No criteria changes.	12/14/2022