VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Iron Replacement – Injectafer Utilization Management Medical Policy
- Injectafer® (ferric carboxymaltose intravenous infusion or slow injection – American Regent)

REVIEW DATE: 12/14/2022

OVERVIEW

Injectafer, an iron replacement product, is indicated for the treatment of:[1]
- **Iron deficiency anemia (IDA)**, in patients ≥ 1 year of age, with either an **intolerance or unsatisfactory response to oral iron**.
- **IDA,** in patients ≥ 18 years of age, with **non-dialysis dependent chronic kidney disease** (CKD).
- **Iron deficiency**, in patients ≥ 18 years of age, with **heart failure** and New York Heart Association class II/III to improve exercise capacity.

Dosing Information

Injectafer is administered by intravenous (IV) infusion or slow injection and treatment may be repeated if iron deficiency remains persistent or recurring. For treatment of IDA, patients weighing ≥ 50 kg, the recommended dose is up to 750 mg per dose with a total cumulative dose not to exceed 1500 mg per treatment course. For patients weighing < 50 kg, the recommended dose is 15 mg/kg in two doses separated by at least 7 days per course. See Table 1 for recommended dosage of Injectafer for the treatment of iron deficiency with heart failure.

Table 1. Recommended Dosage of Injectafer (ferric carboxymaltose injection) in Patients with Iron Deficiency with Heart Failure.[1]

	Weight < 70 kg			**Weight ≥ 70 kg**		
	Hb < 10 g/dL	**Hb 10-14 g/dL**	**Hb >14 to <15 g/dL***	**Hb < 10 g/dL**	**Hb 10-14 g/dL**	**Hb >14 to < 15 g/dL***
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	No dose	No dose	1,000 mg	500 mg	No dose
Beyond Week 6	Administer a **maintenance dose** of 500 mg at 12, 24 and 36 weeks if serum ferritin < 100 ng/mL or serum ferritin 100 to 300 ng/mL with transferrin saturation < 20%.*					

Hb – hemoglobin; *There are no data available to guide dosing beyond 36 weeks or with Hb ≥15 g/dL.

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 2.2023 – March 6, 2023) 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 Injectafer. 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 Injectafer as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Injectafer to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are NOT on Dialysis**. Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Injectafer is prescribed by or in consultation with a nephrologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

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2. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** Patient meets one of the following (i, ii, iii, or iv):
     - **i.** Patient meets both of the following (a and b):
       - **a)** Patient has tried oral iron supplementation; AND
       - **b)** According to the prescriber, oral iron supplementation was ineffective or intolerable; OR

ii. Patient has a condition which, per the prescriber, will interfere with oral iron absorption (e.g., inflammatory bowel disease, Crohn's disease); OR
iii. 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.
iv. The medication is being requested for cancer- or chemotherapy-related anemia.

Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

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3. Iron Deficiency Associated with Heart Failure. Approve for 1 year if the patient meets the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) Injectafer is being prescribed by or in consultation with a cardiologist or hematologist.

Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

Other Uses with Supportive Evidence

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Injectafer 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. Injectafer® intravenous infusion or slow injection [prescribing information]. Shirley, NY: American Regent; May 2023.
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 2.2023 – March 6, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 25, 2023.
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	**Iron Deficiency Anemia, Other:** The age requirement was changed from 18 years of age to 1 year of age.	12/15/2021
Annual Revision	No criteria changes.	12/14/2022
Update	**07/25/2023**: No criteria changes. **Iron Deficiency Associated with Heart Failure** indication was moved from "Other Uses with Supportive Evidence" to "FDA-Approved Indications." Overview was updated with recommended dosage in patients with iron deficiency with heart failure.	N/A