Injectafer® (ferric carboxymaltose)

When requesting Injectafer® (ferric carboxymaltose), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Injectafer is indicated for the treatment of:

- iron deficiency anemia in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron;
- iron deficiency anemia in adult patients who have non-dialysis dependent chronic kidney disease;
- iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

Approved Off-label Compendial Use

- Iron deficiency anemia in patients with chronic kidney disease who are on dialysis

Coverage Guidelines

Iron Deficiency Anemia in Patients with Chronic Kidney Disease

The individual must meet both of the following criteria for approval:

- Is 18 years of age or older;
- Injectafer is prescribed by or in consultation with a nephrologist or hematologist.

Iron Deficiency Anemia, Other

The individual must meet both of the following criteria for approval:

- Is one year of age or older;
- Must meet one of the following:
    - Has tried oral iron supplementation but was ineffective or intolerable; OR
    - Has a condition which will interfere with oral iron absorption (e.g., inflammatory bowel disease); OR
    - Is currently receiving an erythropoiesis-stimulating agent (e.g., an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product); OR
    - Injectafer is being requested for cancer or chemotherapy-related anemia.

Iron Deficiency in Patients with Heart Failure

The individual must meet both of the following criteria for approval:

- Is 18 years of age or older;
- Injectafer is prescribed by or in consultation with a cardiologist or hematologist.

Approval duration: 12 months

Dosing Recommendations

Iron Deficiency Anemia

For patients weighing 50 kg or more:

The recommended dosage is 750 mg administered intravenously in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course. In adult patients, Injectafer 15 mg/kg body weight up to a maximum of 1,000 mg intravenously may be administered as a single-dose per course.

For patients weighing less than 50 kg:

The recommended dosage is 15 mg/kg body weight administered intravenously in two doses separated by at least 7 days per course.

Iron Deficiency in Heart Failure

	Weight < 70 kg			**Weight ≥ 70 kg**		
	Hb (g/dL)			**Hb (g/dL)**		
	< 10	**10-14**	**>14 to<15**	**< 10**	**10-14**	**>14 to<15**
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

Administer a maintenance dose of 500 mg at 12, 24 and 36 weeks if serum ferritin <100 ng/mL or serum ferritin 100-300 ng/mL with transferrin saturation <20%.

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 2.2024 – December 12, 2023). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org Accessed on January 4, 2024.
4. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in *J Am Coll Cardiol*. 2023 Apr 18;81(15):1551]. *J Am Coll Cardiol*. 2022;79(17):e263-e421.