

Feraheme® (ferumoxytol)

When requesting Feraheme® (ferumoxytol), 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

Feraheme is indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron or
- who have chronic kidney disease.

Approved Off-label Compendial Use

- Iron deficiency in patients with heart failure

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;
- Feraheme 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 18 years of age or older;
- Must meet one of the following:
 - o Has tried oral iron supplementation but was ineffective or intolerable; OR
 - o Has a condition which will interfere with oral iron absorption (e.g., inflammatory bowel disease); OR
 - o 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
 - o Feraheme 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;
- Feraheme is prescribed by or in consultation with a cardiologist or hematologist.

Approval duration: 12 months

Dosing Recommendation

The recommended dose of Feraheme is an initial 510 mg dose given intravenously, followed by a second 510 mg dose 3 to 8 days later.

References

1. Feraheme® [prescribing information]. Waltham, MA: AMAG; June 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 2.2024 – December 12, 2023). 2023 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.