UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Iron Replacement – Feraheme Utilization Management Medical Policy
- Feraheme® (ferumoxytol intravenous infusion – AMAG, generic)

REVIEW DATE: 01/15/2025

OVERVIEW

Feraheme, an iron replacement product, is indicated for the treatment of **iron deficiency anemia** in patients ≥ 18 years of age for the following uses:[1]

- **Chronic kidney disease** (CKD).
- **Intolerance to oral iron or have had unsatisfactory response to oral iron**.

Dosing Information

Feraheme is administered by intravenous (IV) infusion and treatment may be repeated if iron deficiency remains persistent or recurring.[1] The recommended dose of Feraheme is an initial 510 mg dose followed by a second 510 mg dose 3 to 8 days later per treatment cycle.

Guidelines

The Kidney Disease: Improving Global Outcomes clinical practice guideline for anemia in CKD (2025) make various recommendations regarding iron therapy.[2] For patients with CKD and anemia receiving hemodialysis, initiation of IV iron is suggested if transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For patients with CKD and anemia who are not receiving hemodialysis or treated with peritoneal dialysis, initiation of oral or IV iron is suggested if TSAT is < 40% and ferritin < 100 ng/mL or if TSAT < 25% with ferritin ≥ 100 ng/mL and < 300 ng/ml. For patients with CKD and profound iron deficiency (TSAT < 20% and ferritin < 30 ng/mL) but no anemia, consider treatment with oral or IV iron. Additional practice points are noted such as a switch from oral to IV iron if there is an insufficient effect of an optimal oral regimen after 1 to 3 months. KDIGO also notes the choice between different formulations of IV iron should be guided by individual considerations and recommended dosing schedules.

The National Comprehensive Cancer Network guidelines on hematopoietic growth factors (version 1.2025 – October 11, 2024) discuss the management of cancer- and chemotherapy-induced anemia.[3] Treatment for iron deficiency is guided by iron status which is defined in the guidelines as: absolute iron deficiency, functional iron deficiency, possible functional iron deficiency, or no iron deficiency and by use in combination with erythropoiesis-stimulating agents (ESA). 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%) in patients who are also receiving an ESA, and for select patients with possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%). All recommendations are category 2A for each product.

The American College of Cardiology/American Heart Association guideline for the management of heart failure (2022) states that in patients with heart failure with reduced ejection fraction (left ventricular ejection fraction ≤ 40%), absolute iron deficiency (ferritin < 100 ng/mL) or functional iron deficiency (ferritin = 100 to 300 mg/mL if TSAT is < 20%), and with or without anemia, IV iron replacement is reasonable to improve functional status and quality of life (2a recommendation).[4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Feraheme. 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 Feraheme as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Feraheme to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Feraheme 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 on Dialysis**. Approve for 3 years.

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

   Dosing. Approve up to a maximum cumulative total dose of 1020 mg given intravenously per 30 days.

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3. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years 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.** According to the prescriber, patient has a condition that will interfere with oral iron absorption; OR
       Note: Examples of conditions that may interfere with oral iron absorption may include inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
     - **iii.** Patient is currently receiving an erythropoiesis-stimulating agent; OR
       Note: Examples of erythropoiesis-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 1020 mg given intravenously per 30 days.

Other Uses with Supportive Evidence

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

Dosing. Approve up to a maximum cumulative total dose of 1020 mg given intravenously per 30 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Feraheme 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. Feraheme® [prescribing information]. Waltham, MA: AMAG; June 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. 2025 KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease (*November 2024 Public Review Draft*). Available at: https://kdigo.org/guidelines/anemia-in-ckd/. Accessed on January 8, 2025
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 7, 2025.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	01/10/2024
Annual Revision	**Iron Deficiency Anemia, Other:** The verbiage "patient has a condition which, per the prescriber, will interfere with oral iron absorption" was updated to "according to the prescriber, patient has a condition that will interfere with oral iron absorption". Examples of "conditions that may interfere with oral iron absorption" were moved from the criteria to a Note. The term "erythroid-stimulating agents" was updated to "erythropoiesis-stimulating agents".	01/15/2025