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** Please note: The Clinical Coverage Guideline (CCG) is intended to supplement certain standard Alignment Health (Alignment) benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific mandates. Information is current at time of approval by the Quality Improvement Committee (QIC) and are subject to change.*

AHC Ferumoxytol

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MCG Health
Ambulatory Care
28th Edition

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Evidence Summary

Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transport oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hematocrit levels. Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. The available evidence suggests that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products, which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia. Coverage also includes the medically necessary and reasonable use of parenteral iron preparations in non-dialysis related clinical conditions.

Clinical Indications

- Ferumoxytol (Feraheme) may be indicated for the treatment of iron deficiency anemia [A] for **1 or more** of the following:
 - Member has an intolerance to oral iron
 - Member has had an unsatisfactory response to oral iron
 - Member has chronic kidney disease
 - Member has a condition where oral iron is unlikely to be successful (e.g., inflammatory bowel disease, short bowel syndrome, history of gastric bypass)
 - Member has chemotherapy-induced anemia who are currently also on an erythropoietin-stimulating agent
 - Member has ongoing iron loss (e.g., severe menorrhagia, Rendu-Osler-Weber disease)

Committee Approval

- 01/09/2024, 02/20/2025

References

- Local Coverage Article: Parental Iron Administration Coverage in Non-Dialysis Usage (A55653)
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022180s009lbl.pdf
- Micromedex Ferumoxytol

Application

- *This policy applies to the following states: Arizona, California, Nevada, North Carolina, and Texas.
- Medicare may cover intravenous iron replacement therapy when criteria have been met. Refer to the National Coverage Determination (NCD) for Intravenous Iron Therapy (110.10), which addresses coverage guidelines for sodium ferric gluconate and iron sucrose.
- Please refer to the CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Policy Revision History

- 05/26/2022: Creation date
- 12/05/2023: Revision
- 11/12/2024: Annual review, Applicable states updated, Florida removed

Footnotes

[A] Member has iron deficiency defined as ONE of the following:

- a. Measured ferritin level is less than 15 mcg/L – recent (within 60 days of request) laboratory documentation must be provided
- b. Measured serum iron level AND transferrin saturation level are below the laboratory's lower limit of normal AND measured total iron-binding capacity is above the laboratory's upper limit of normal – recent (within 60 days of request) laboratory documentation must be provided [A in Context Link 1]

Codes

CPT® : Q0138, Q0139

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