

Feraheme® (ferumoxytol injection)

(Intravenous)

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Dates Reviewed: 10/2019, 07/2020, 12/2021, 12/2022, 12/2023, 05/2024

I. Length of Authorization

Coverage will be provided for 35 days.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Feraheme 510 mg/17 mL single-use dose vial: 2 vials per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- Q0138 (non-ESRD): 1020 billable units per 28 days
- Q0139 (ESRD on dialysis): 1020 billable units per 28 days

III. Initial Approval Criteria ¹⁻¹⁴

Coverage is provided in the following conditions:

- Patient had an inadequate response, or has a contraindication or intolerance, to sodium ferric gluconate complex (Ferrlecit®) OR iron dextran (INFeD®) OR iron sucrose (Venofer®); **AND**
- Patient must be at least 18 years of age; **AND**
- Other causes of anemia (e.g., vitamin B-12 deficiency, thalassemia, sideroblastic anemia, etc.) have been ruled out; **AND**
- Patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferumoxytol; **AND**
- Patient is not anticipated to require magnetic resonance imaging (MRI) during the 3-month period following the last ferumoxytol dose as it is known to alter these imaging studies; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**

Iron Deficiency Anemia due to Chronic Kidney Disease (CKD) †^{1,5-7,14-15}

- Patient has a transferrin saturation (TSAT) ≤ 30 % AND ferritin is ≤ 500 ng/mL; **AND**
 - Patient is hemodialysis-dependent (HDD-CKD); **AND**
 - Patient has a hemoglobin (Hb) < 11.5 g/dL; **OR**
 - Patient is not receiving dialysis (NDD-CKD); **AND**
 - Patient has a hemoglobin (Hb) < 11 g/dL

Iron Deficiency Anemia in patients intolerant to or who have had unsatisfactory response to oral iron †^{1,4}

- Patient had an intolerance or inadequate response to a minimum of 14 days of oral iron; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) < 12 g/dL for females or < 14 g/dL for males; **AND**
 - Patient has a transferrin saturation (TSAT) ≤ 20%; **OR**
 - Patient has a ferritin ≤ 100 ng/mL

Cancer- and Chemotherapy-Induced Anemia ‡^{11,12}

- Used as a single agent; **AND**
 - Patient has absolute iron deficiency defined as ferritin < 30 ng/mL AND a TSAT < 20%; **OR**
 - Patient has functional iron deficiency defined as ferritin > 500 – 800 ng/mL AND a TSAT < 50% with the goal of avoiding allogenic transfusion; **OR**
- Used in combination with erythropoiesis-stimulating agents (ESAs); **AND**
 - Patient has absolute iron deficiency defined as ferritin < 30 ng/mL AND a TSAT < 20% and failed to demonstrate an increase in Hb after 4 weeks of IV or oral iron therapy; **OR**
 - Patient has functional iron deficiency defined as ferritin 30 – 500 ng/mL AND a TSAT < 50% and is receiving myelosuppressive chemotherapy without curative intent

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹⁻¹⁴

Refer to initiation criteria.

V. Dosage/Administration^{1,11}

Indication	Dose
All indications	Administer 510 mg dose intravenously followed by a second 510 mg dose intravenously 3 to 8 days later

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| | <ul style="list-style-type: none"> Evaluate response at least one month following the second infusion |
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VI. Billing Code/Availability Information

HCPCS Code(s):

- Q0138: Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD)
- Q0139: Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

NDC:

- Feraheme 510 mg/17 mL single-dose vial*: 59338-0775-xx
**Available generically*

VII. References

- Feraheme [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc. June 2022. Accessed April 2024.
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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ferumoxytol. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2024.
12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed April 2024.
13. Wish JB. Assessing iron status: beyond serum ferritin and transferrin saturation. *Clin J Am Soc Nephrol.* 2006 Sep;1 Suppl 1:S4-8.
14. Macdougall IC, Strauss WE, McLaughlin J, Li Z, et al. A randomized comparison of ferumoxytol and iron sucrose for treating iron deficiency anemia in patients with CKD. *Clin J Am Soc Nephrol.* 2014;9(4):705-712. doi: 10.2215/CJN.05320513.
15. Rosen-Zvi B, Gafter-Gvili A, Paul M, et al. Intravenous versus oral iron supplementation for the treatment of anemia in CKD: systematic review and meta-analysis, *Am J Kidney Dis*, 2008, vol. 52 (pg. 897-906)10.1053/j.ajkd.2008.05.033

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic disease classified elsewhere
D64.81	Anemia due to antineoplastic chemotherapy
Z51.11	Encounter for antineoplastic chemotherapy

Z51.89	Encounter for other specified aftercare
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC