Feraheme® (ferumoxytol)

(Intravenous)

Document Number: CGHC-0495

Last Review Date: 12/01/2022
Date of Origin: 10/01/2019
Dates Reviewed: 10/2019, 07/2020, 12/2021, 12/2022

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): 1020 billable units per 28 days

III. Initial Approval Criteria [1-14]

Coverage is provided in the following conditions:

- Infed (iron dextran), Venofer (iron sucrose) and Ferrlecit (ferric gluconate) are the preferred products. Patient must have failed, or have a contraindication, or intolerance to 2 of the 3 preferred products before consideration of Injectafer or Feraheme; **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]

- Patient has a transferrin saturation (TSAT) ≤ 30 % AND ferritin is ≤ 500 ng/mL; **AND**
  - The patient is hemodialysis-dependent (HDD-CKD); **AND**
    - Patient has a hemoglobin (Hb) < 11.5 g/dL; **OR**
  - The patient is not receiving dialysis (NDD-CKD); **AND**
    - Patient has a Hb < 11 g/dL; **AND**
    - Patient had an insufficient response or intolerance to a ≥ 1-month trial of oral iron

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**
- The patient has a Hb < 12 g/dL for females or < 14 g/dL for males; **AND**
  - The patient has a transferrin saturation (TSAT) ≤ 20%; **OR**
  - The 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 Criteria [1-14]

Refer to initiation criteria

V. Dosage/Administration [1,11]

Indication	Dose
All indications	Administer 510 mg dose followed by a second 510 mg dose 3 to 8 days later • Evaluate response at least one month following the second infusion

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

1. Feraheme [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc. June 2022. Accessed November 2022.
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5. Provenzano R, Schiller B, Rao M, et al. Ferumoxytol as an intravenous iron replacement therapy in hemodialysis patients. Clin J Am Soc Nephrol. 2009 Feb;4(2):386-93.
6. Singh A, Patel T, Hertel J, et al. Safety of ferumoxytol in patients with anemia and CKD. Am J Kidney Dis. 2008 Nov;52(5):907-15.
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8. KDOQI; National Kidney Foundation. Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease in adults. Am J Kidney Dis. 2006 May;47(5 Suppl 3):S16-85.
9. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335.
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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ferumoxytol. National Comprehensive Cancer Network, 2022. The NCCN

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12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors 1.2022. National Comprehensive Cancer Network, 2022. 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 November 2022.
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.

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

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 Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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