Feraheme® (ferumoxytol)

(Intravenous)

Document Number: MODA-0495

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

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 solution: 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:

- 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 be18 years or older; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency, etc.) have been ruled out; **AND**
- The 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) †

- 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 †

- 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 TSAT ≤ 20%; **OR**
  - The patient has a ferritin ≤ 100 ng/mL

Cancer- and chemotherapy-induced anemia ‡

- May be considered in instances where the recommended IV iron preparations with demonstrated efficacy in patients with cancer (i.e., low-molecular-weight iron dextran, ferric gluconate, & iron sucrose) are not appropriate; **AND**
  - Used as a single agent; **AND**
    - Patient has a ferritin < 30 ng/mL AND a TSAT < 20%; **OR**
    - Patient has a ferritin > 500 - 800 ng/mL AND a TSAT < 50% AND does not wish to have an allogenic transfusion; **OR**
  - Used in combination with erythropoiesis-stimulating agents (ESAs); **AND**
    - Patient has a 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 a ferritin 30 - 500 ng/mL AND a TSAT < 50% and is receiving myelosuppressive chemotherapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); **Φ** Orphan Drug

IV. Renewal Criteria

Refer to initiation criteria

V. Dosage/Administration

Indication	Dose
All indications	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:

- 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-use vial: 59338-0775-xx

VII. References

1. Feraheme [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc. February 2018. Accessed June 2020.
2. Vadhan-Raj S, Strauss W, Ford D, et al. Efficacy and safety of IV ferumoxytol for adults with iron deficiency anemia previously unresponsive to or unable to tolerate oral iron. Am J Hematol. 2014 Jan;89(1):7-12.
3. Hetzel D, Strauss W, Bernard K, Li Z, Urboniene A, Allen LF. A Phase III, randomized, open-label trial of ferumoxytol compared with iron sucrose for the treatment of iron deficiency anemia in patients with a history of unsatisfactory oral iron therapy. Am J Hematol. 2014 Jun;89(6):646-50. doi: 10.1002/ajh.23712.
4. Adkinson NF, Strauss WE, Macdougall IC, Bernard KE, Auerbach M, Kaper RF, Chertow GM, Krop JS. Comparative safety of intravenous ferumoxytol versus ferric carboxymaltose in iron deficiency anemia: A randomized trial. Am J Hematol. 2018 May;93(5):683-690. doi: 10.1002/ajh.25060. Epub 2018 Feb 24.
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.
7. Spinowitz BS, Kausz AT, Baptista J, et al. Ferumoxytol for treating iron deficiency anemia in CKD. J Am Soc Nephrol. 2008 Aug;19(8):1599-605.
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.
10. Ratcliffe LE, Thomas W, Glen J, et al. Diagnosis and Management of Iron Deficiency in CKD: A Summary of the NICE Guideline Recommendations and Their Rationale. Am J Kidney Dis. 2016 Apr;67(4):548-58.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ferumoxytol. National Comprehensive Cancer Network, 2020. 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 June 2020.

12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors 2.2020. National Comprehensive Cancer Network, 2020. 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 June 2020.
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. CGS Administrators, LLC. Local Coverage Article (LCA). Billing and Coding: Iron Sucrose, Iron Dextran, and Ferumoxytol, (Intravenous Iron Therapy))- J1439, J1750, J1756, Q0138, Q0139 (A56629). Centers for Medicare & Medicaid Services, Inc. Updated on 09/18/2019 with effective date 09/26/2019. Accessed June 2020.

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):

Jurisdiction(s): 15	NCD/LCD Document (s): A56629
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56629&ver=2&DocID=A56629&bc=gAAAABAAAAAA&	

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