Feraheme® (ferumoxytol injection)

(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 35 days.
- Renewal: Prior authorization validity may be renewed for 35 days when initial criteria are met.

II. Dosing Limits

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]

Prior authorization validity is provided in the following conditions:

- Patient must have a contraindication, intolerance, or failure to **Ferrlecit®, INFeD®,** OR **Venofer®** prior to consideration of Feraheme®; **AND**

- Member 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**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferumoxytol; **AND**
- Member 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) † ‡ [1,5-7,14-15,17]

- Member has iron-deficiency anemia with a hemoglobin (Hb) <12 g/dL for females or < 13 g/dL for males; **AND**
  - Member is hemodialysis-dependent (HDD-CKD); **AND**
    - Member has a transferrin saturation (TSAT) ≤ 30 % AND ferritin is ≤ 500 ng/mL; **OR**
  - Member is not receiving dialysis (NDD-CKD) or member is receiving peritoneal dialysis; **AND**

- Member has a ferritin < 100 ng/mL AND TSAT < 40%; **OR**
- Member has a ferritin < 300 ng/mL AND TSAT < 25%

Iron Deficiency Anemia in members intolerant to or who have had unsatisfactory response to oral iron † ‡ [1,4,18]

- Member has iron-deficiency anemia with a hemoglobin (Hb) < 12 g/dL for females or < 14 g/dL for males; **AND**
- Member has ferritin ≤ 100 ng/mL OR transferrin saturation (TSAT) ≤ 20%; **AND**
  - Member had an intolerance or inadequate response to a minimum of 14 days of oral iron; **OR**
  - Member has a condition in which oral iron is unlikely to be absorbed (e.g., active inflammatory bowel disease, prior bariatric surgery)

Cancer- and Chemotherapy-Induced Anemia ‡ [11,12]

- Used as a single agent; **AND**
  - Member has absolute iron deficiency defined as ferritin < 30 ng/mL AND a TSAT < 20%; **OR**
  - Member 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**
  - Member 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**
  - Member 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 initial criteria.

V. Dosage/Administration [1,11,12,16]

Indication	Dose
Cancer- and Chemotherapy-Induced Anemia	Administer 510 mg dose intravenously followed by a second 510 mg dose intravenously 3 to 8 days later **OR** Administer 1020 mg single dose intravenously
All other indications	Administer 510 mg dose intravenously followed by a second 510 mg dose intravenously 3 to 8 days later • Evaluate response at least one month following the second infusion

VI. Billing Code/Availability Information

HCPCS Code(s):

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

NDC:

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

  **Available generically*

VII. References

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12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors 3.2026. National Comprehensive Cancer Network, 2025. 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 March 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management

NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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)

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