Neighborhood Health Plan OF RHODE ISLAND™
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Monoferric (ferric derisomaltose)
NON-HEMATOLOGY CRITERIA
(Intravenous)

Effective Date: 10/01/2021
Review Date: 09/02/2021, 05/05/2022, 12/7/2023, 01/04/2024, 04/30/2025

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for 35 days.

II. Dosing Limits

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

- Monoferric 100 mg /1 mL single-use vial: 4 vials per 35 days
- Monoferric 500 mg /5 mL single-use vial: 1 vial per 35 days
- Monoferric 1000 mg /10 mL single-use vial: 1 vial per 35 days

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

- 100 billable units per 35 days

III. Summary of Evidence

Monoferric is an iron replacement product containing ferric derisomaltose indicated for the treatment of iron deficiency anemia in adults that are intolerant to oral iron, have had an unsatisfactory response to oral iron or who currently have non hemodialysis dependent chronic kidney disease. Serious hypersensitivity reactions, including anaphylactic type reactions, have been reported in patients while on this therapy. Therefore, patients should be monitored for at least 30 minutes until they are clinically stable during and following the completion of the infusion. Monoferric was evaluated in two randomized, open label, actively controlled clinical trials. Both studies in combination included 3050 patients with iron deficiency anemia. Trial 1 enrolled 1512 adult patients with intolerance to oral iron or had an unsatisfactory response to oral iron with a clinical need for repletion of iron stores. Trial 2 enrolled 1525 adult patients with non-dialysis dependent kidney disease and iron deficiency anemia. Non-inferiority was confirmed in both trails.

IV. Initial Approval Criteria[1-9]

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Patient must be 18 years or older; **AND**

Universal Criteria

- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **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 ferric derisomaltose; **AND**

Iron deficiency anemia in non-dialysis-dependent chronic kidney disease (NDD-CKD) †

- Patient must not be receiving hemodialysis; **AND**
- Patient has had a failure, contraindication, or ineffective response to one of the following intravenous iron products: Injectafer or Feraheme
- Patient has chronic renal impairment with eGFR between 15-59 mL/min; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) ≤11 g/dL; **AND**
    - Ferritin ≤100 ng/mL; **OR**
    - Ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%

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

V. Renewal Criteria

Refer to initiation criteria.

VI. Dosage/Administration

Indication	Dose
Iron deficiency anemia in adults due to NDD-CKD	<u>Weight ≥ 50 kg:</u> • Administer 1,000 mg intravenously as a single dose. <u>Weight < 50 kg:</u> • Administer 20 mg/kg actual body weight intravenously as a single dose. Note: Treatment may be repeated if iron deficiency anemia recurs.
Dosages are expressed in mg of elemental iron. Each mL of Monoferric contains 100 mg of elemental iron.	

VII. Billing Code/Availability Information

HCPCS code:

- J1437- Injection, ferric derisomaltose, 10 mg; 1 billable unit=10 mg

NDC:

- Monoferric 100 mg /1 mL single-use vial: 49442-9301-xx
- Monoferric 500 mg /5 mL single-use vial: 49442-9305-xx
- Monoferric 1000 mg /10 mL single-use vial: 49442-9310-xx

VIII. References

1. Monoferric [package insert]. Holbaek, Denmark; Pharmacosmos, A/S. August 2022. Accessed April 2025.
2. 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.
3. 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.
4. 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.
5. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) ferric derisomaltose. 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 January 2020.
6. 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.
7. Wish JB. Assessing iron status: beyond serum ferritin and transferrin saturation. Clin J Am Soc Nephrol. 2006 Sep;1 Suppl 1:S4-8.
8. Koch TA, Myers J, Goodnough LT. Intravenous Iron Therapy in Patients with Iron Deficiency Anemia: Dosing Considerations. Anemia. 2015;2015:763576.

9. Auerbach M, Henry D, Derman RJ, et al. A prospective, multi-center, randomized comparison of iron isomaltoside 1000 versus iron sucrose in patients with iron deficiency anemia; the FERWON-IDA trial. Amer J of Hema. Sep2019:94;9;pps1007-1014.
10. Bhandari S, Thomsen LL. Single 1000 Mg Infusion Of Iron Isomaltoside 1000 Demonstrates A More Rapid Hemoglobin Response And Reduced Risk Of Cardio-Vascular Adverse Events Compared To Multiple Doses Of IV Iron Sucrose In The FERWON Trials. Nephrology Dialysis Transplantation 34 (Supplement 1): i475–i486, 2019

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
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic disease classified elsewhere

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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, 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

Policy Rationale:

Monoferric was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Monoferric according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.