Monoferric™ (ferric derisomaltose)
(Intravenous)

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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. Initial Approval Criteria [1-11]

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®); OR**
- **Patient is continuing treatment with Monoferric; OR**
- **Patient would have a life threatening situation if required to meet step therapy requirements; AND**
- Patient is at least 18 years of age; **AND**
- 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) † [1,10,11]

- Patient must not be receiving hemodialysis; **AND**
- 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%

Iron deficiency anemia in patients intolerant to or who have had unsatisfactory response to oral iron † [1,9]

- 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) ≤11 g/dL; **AND**
    - Ferritin <100 ng/mL; **AND**
    - Transferrin saturation (TSAT) <20%

Cancer- and Chemotherapy-Induced Anemia ‡ [5,6]

- May be considered in instances where the patient has failed on the recommended IV iron preparations with demonstrated efficacy in patients with cancer (i.e., low-molecular-weight iron dextran, ferric gluconate, ferumoxytol, & iron sucrose); **AND**
    - 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 [1,5]

Refer to initiation criteria.

V. Dosage/Administration [1,5]

Indication	Dose
All indications	Weight ≥ 50 kg: • Administer 1,000 mg intravenously as a single dose. Weight < 50 kg: • Administer 20 mg/kg actual body weight intravenously as a single dose. Note: Treatment may be repeated if iron deficiency anemia reoccurs.
Dosages are expressed in mg of elemental iron. Each mL of Monoferric contains 100 mg of elemental iron.	

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

- Monoferric 100 mg/1 mL single-dose vial: 73594-9301-xx
- Monoferric 500 mg/5 mL single-dose vial: 73594-9305-xx
- Monoferric 1000 mg/10 mL single-dose vial: 73594-9310-xx

VII. References

1. Monoferric [package insert]. Holbaek, Denmark; Pharmacosmos, A/S. September 2020. Accessed November 2021.
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, 2021. 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 October 2021.

6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors 4.2021. National Comprehensive Cancer Network, 2021. 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 October 2021.
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.
11. Bhandari S, Kalra PA, Berkowitz M, et al. Safety and efficacy of iron isomaltoside 1000/ferric derisomaltose versus iron sucrose in patients with chronic kidney disease: the FERWON-NEPHRO randomized, open-label, comparative trial. Nephrol Dial Transplant. 2021 Jan 1;36(1):111-120. doi: 10.1093/ndt/gfaa011.

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
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: https://www.cms.gov/medicare-coverage-database/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 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