Injectafer® (ferric carboxymaltose injection)
(Intravenous)

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Effective Dates: 04/2022

I. Length of Authorization

Coverage will be provided for 35 days.

II. Dosing Limits

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

- Injectafer 750 mg iron/15 mL single-dose vial: 2 vials per 35 days
- Injectafer 1,000 mg iron/20 mL single-dose vial: 1 vial per 35 days

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

- 1500 billable units per 35 days

III. Initial Approval Criteria [1-12]

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 Injectafer; OR**
- **Patient would have a life threatening situation if required to meet step therapy requirements; AND**
- Patient is at least 18 years of age, unless otherwise specified; **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 carboxymaltose; **AND**

Iron deficiency anemia in non-dialysis-dependent chronic kidney disease (NDD-CKD) † [1,6,12]

- Patient must not be receiving dialysis; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) <11.5 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 † [1-3]

- Patient is at least 1 year of age; **AND**
- 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) <12 g/dL; **AND**
    - Ferritin ≤100 ng/mL; **OR**
    - Ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%

Cancer- and Chemotherapy-Induced Anemia ‡ [7,8]

- 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 a 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 [1-12]

Refer to initiation criteria.

V. Dosage/Administration [1,7]

Indication	Dose
Iron deficiency anemia due to NDD-CKD or intolerance/inadequate response to oral iron	Weight ≥ 50 kg: • Administer two doses of 750 mg IV separated by at least 7 days for a total cumulative dose not to exceed 1500 mg of iron per course; **OR** • Administer one dose of 15 mg/kg body weight up to a maximum of 1,000 mg of iron per course Weight < 50 kg: • Administer two doses of 15 mg/kg body weight IV separated by at least 7 days for a total cumulative dose not to exceed 1500 mg of iron per course. Treatment may be repeated if iron deficiency anemia reoccurs.
Cancer/Chemotherapy induced anemia	Administer total median dose of 1000 mg (range of 600 – 1500 mg) IV, separated by at least 7 days (Consider dividing larger doses to a maximum single dose of 750 mg)

VI. Billing Code/Availability Information

HCPCS Code:

- J1439 - Injection, ferric carboxymaltose, 1 mg; 1 billable unit = 1 mg

NDC:

- Injectafer 750 mg iron/15 mL single-dose vial: 00517-0650-xx
- Injectafer 1,000 mg iron/20 mL single-dose vial: 00517-0620-xx

VII. References

1. Injectafer [package insert]. Shirley, NY; American Regent, Inc. November 2021. Accessed November 2021.
2. Onken JE, Bregman DB, Harrington RA, et al. A multicenter, randomized, active-controlled study to investigate the efficacy and safety of intravenous ferric carboxymaltose in patients with iron deficiency anemia. Transfusion. 2014 Feb;54(2):306-15.
3. Onken JE, Bregman DB, Harrington RA, et al. Ferric carboxymaltose in patients with iron-deficiency anemia and impaired renal function: the REPAIR-IDA trial. Nephrol Dial Transplant. 2014 Apr;29(4):833-42.
4. 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.

5. 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.
6. 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.
7. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) ferric carboxymaltose. 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 November 2021.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors Version 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 November 2021.
9. Wish JB. Assessing iron status: beyond serum ferritin and transferrin saturation. Clin J Am Soc Nephrol. 2006 Sep;1 Suppl 1:S4-8.
10. Koch TA, Myers J, Goodnough LT. Intravenous Iron Therapy in Patients with Iron Deficiency Anemia: Dosing Considerations. Anemia. 2015;2015:763576.
11. Steinmetz T, Tschechne B, Harlin O, et al. Clinical experience with ferric carboxymaltose in the treatment of cancer- and chemotherapy-associated anaemia. Ann Oncol. 2013;24(2):475-482.
12. Qunibi WY, Martinez C, Smith M, et al. A randomized controlled trial comparing intravenous ferric carboxymaltose with oral iron for treatment of iron deficiency anaemia of non-dialysis-dependent chronic kidney disease patients. Nephrol Dial Transplant. 2011;26(5):1599-1607.

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 Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCD/LCA): 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