Injectafer® (ferric carboxymaltose injection) (Intravenous)

Document Number: MODA-0312

Last Review Date: 05/02/2024
Date of Origin: 08/29/2017
Dates Reviewed: 08/2017, 07/2018, 07/2019, 07/2020, 06/2021, 12/2021, 09/2022, 07/2023, 12/2023, 05/2024

I. Length of Authorization [1]

Coverage will be provided for 35 days, unless otherwise specified.

- Iron Deficiency in Patients with Heart Failure: Coverage will be provided for 12 weeks (for up to 2 doses) initially and may be renewed every 12 weeks (for 1 dose) up to a total of 3 maintenance doses.

II. Dosing Limits

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

- Injectafer 100 mg iron/2 mL single-dose vial: 7 vials per 35 days
- Injectafer 750 mg iron/15 mL single-dose vial: 2 vials per 35 days
- Injectafer 1,000 mg iron/20 mL single-dose vial: 2 vials per 35 days

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

- 1500 billable units per 35 days

III. Initial Approval Criteria [1-13]

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 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., vitamin B-12 deficiency, thalassemia, sideroblastic anemia, etc.) have been ruled out; **AND**
- 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 ‡ [7,8,14,15]

- 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

Iron Deficiency in Patients with Heart Failure † [1]

- Patient has New York Heart Association class II/III disease; **AND**
- Used to improve exercise capacity; **AND**
- Patient has iron deficiency with hemoglobin < 15 g/dL; **AND**
  - Ferritin < 100 ng/mL; **OR**
  - Ferritin is 100 to 300 ng/mL with TSAT <20%

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

IV. Renewal Criteria [1-13]

Coverage may be renewed based on the following criteria:

Iron Deficiency in Patients with Heart Failure

- Patient has hemoglobin < 15 g/dL; **AND**
- Patient has serum ferritin <100 ng/mL OR serum ferritin 100-300 ng/mL with transferrin saturation <20%; **AND**
- Patient will receive maintenance doses at weeks 12, 24, and 36 *(Refer to dosing table below)*

***Note:** Patient may ONLY receive the maintenance doses if iron labs meet the aforementioned criteria. Patients not meeting this criteria will not be eligible for renewal.*

All Other Indications

- 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 intravenously 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 intravenously up to a maximum of 1,000 mg of iron per course Weight < 50 kg: • Administer two doses of 15 mg/kg body weight intravenously 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.
Iron Deficiency with Heart Failure	**Initial Dosing** Weight < 70 kg: • Hb < 10 g/dL: Administer 1,000 mg intravenously on day 1 and 500 mg at week 6 • Hb 10 to 14 g/dL: Administer 1,000 mg intravenously on day 1 as a single dose (no dose at week 6) • Hb >14 to <15 g/dL Administer 500 mg intravenously on day 1 as a single dose (no dose at week 6) Weight ≥ 70 kg: • Hb <10 g/dL: Administer 1,000 mg intravenously on day 1 and 1,000 mg at week 6 • Hb 10 to 14 g/dL: Administer 1,000 mg intravenously on day 1 and 500 mg at week 6 • Hb > 14 to <15 g/dL: Administer 500 mg intravenously on day 1 as a single dose (no dose at week 6) **Maintenance Dosing**

	• Administer 500 mg intravenously at 12, 24 and 36 weeks if serum ferritin <100 ng/mL or serum ferritin 100-300 ng/mL with transferrin saturation <20%. • There are no data available to guide dosing beyond 36 weeks or with Hb ≥15 g/dL.
Cancer/Chemotherapy Induced Anemia	Weight ≥ 50 kg: • Administer two doses of 750 mg intravenously separated by at least 7 days for a total cumulative dose not to exceed 1500 mg of iron per course Weight < 50 kg: • Administer two doses of 15 mg/kg body weight intravenously separated by at least 7 days for a total cumulative dose not to exceed 1500 mg of iron per course.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Injectafer 100 mg iron/2 mL single-dose vial: 00517-0602-xx
- 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. May 2023. Accessed April 2024.
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8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors Version 3.2024. National Comprehensive Cancer Network, 2024. 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 April 2024.
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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.
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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/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 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