Injectafer® (ferric carboxymaltose injection) (Intravenous)

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I. Length of Authorization [1]

- Initial: Prior authorization validity will be provided initially for 35 days, unless otherwise specified.
  - Iron Deficiency in Heart Failure: Prior authorization validity will be provided initially for 12 weeks (for up to 2 doses).
- Renewal: Prior authorization validity may be renewed for 35 days when initial criteria are met, unless otherwise specified.
  - Iron Deficiency in Heart Failure: Prior authorization validity may be renewed every 12 weeks (for 1 dose) up to a total of 3 maintenance doses.

II. Dosing Limits

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

- 1500 billable units per 35 days

III. Initial Approval Criteria [1-13]

Prior authorization validity is provided in the following conditions:

- Patient is < 6 years of age; **AND**
  - Patient must have an intolerance or failure to INFeD OR Venofer prior to consideration of Injectafer; **OR**
  - Patient must have a contraindication to INFeD AND Venofer prior to consideration of Injectafer; **OR**
- Patient is ≥ 6 years of age and < 18 years of age; **AND**
  - Patient must have an intolerance or failure to Ferrlecit, INFeD, OR Venofer prior to consideration of Injectafer; **OR**
  - Patient must have a contraindication to Ferrlecit, INFeD, AND Venofer prior to consideration of Injectafer; **OR**
- Patient is ≥ 18 years of age; **AND**
  - Patient must have a failure of TWO of the following products, Feraheme, Ferrlecit, INFeD, or Venofer prior to consideration of Injectafer; **AND**

- Member 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**
- 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 ferric carboxymaltose; **AND**

Iron Deficiency Anemia in Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) † ‡ [1,6,12,16]

- Member must not be receiving dialysis; **AND**
- Member has iron-deficiency anemia with a Hemoglobin (Hb) <12 g/dL for females or < 13 g/dL for males; **AND**
  - Ferritin <100 ng/mL and transferrin saturation (TSAT) <40%; **OR**
  - Ferritin <300 ng/mL and TSAT <25%

Iron Deficiency Anemia in members intolerant to or who have had unsatisfactory response to oral iron † ‡ [1-3,17-18]

- Member is at least 1 year of age; **AND**
- Member has iron-deficiency anemia with a Hemoglobin (Hb) <12 g/dL for females or < 13 g/dL for males; **AND**
- Member has ferritin ≤100 ng/mL OR ferritin ≤300 ng/mL when transferrin saturation (TSAT) ≤30%; **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 ‡ [7,8,14,15]

- 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 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**

- 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

Iron Deficiency in Heart Failure † [1]

- Member has New York Heart Association class II/III disease; **AND**
- Used to improve exercise capacity; **AND**
- Member 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]

Prior authorization validity may be renewed based on the following criteria:

Iron Deficiency in Heart Failure

- Member has hemoglobin < 15 g/dL; **AND**
- Member has serum ferritin <100 ng/mL OR serum ferritin 100-300 ng/mL with transferrin saturation <20%; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*

All Other Indications

- Refer to initial 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 in 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. January 2025. Accessed March 2026.
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7. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) ferric carboxymaltose. National Comprehensive Cancer Network, 2026. 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 March 2026.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hematopoietic Growth Factors Version 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	No: PA not a priority
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/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