Clinical Policy: Ferric Carboxymaltose (Injectafer)

Reference Number: CP.PHAR.234
Effective Date: 06.01.16
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ferric carboxymaltose (Injectafer®) injection is an iron replacement product.

FDA Approved Indication(s)

Injectafer is indicated for treatment of:

- Iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron
- IDA in adult patients who have non-dialysis dependent chronic kidney disease (CKD)
- Iron deficiency in adult patients with heart failure and New York Heart Association (NYHA) class II/III to improve exercise capacity.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Injectafer is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA and CKD;
2. IDA is confirmed by either of the following:
   a. Transferrin saturation (TSAT) ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. If CKD does not require hemodialysis or peritoneal dialysis, oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy;
4. Member meets both of the following (a and b):*

   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*

   a. Failure of both of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Ferrlecit®** and **iron sucrose (generic Venofer®)**;
   b. If member has satisfied criterion 4a above, failure of **generic Feraheme®**, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed two 750 mg elemental iron infusions/injections or a single 1,000 mg elemental iron infusion/injection.

Approval duration: 12 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):
1. Diagnosis of IDA confirmed by any of the following:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hgb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased soluble transferring receptor (sTfR) or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
2. Oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy;
3. At the time of the request, member does not have CKD;
4. Member meets both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed®**, or **iron sucrose (generic Venofer)**;
   b. If member has satisfied criterion 4a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed two 750 mg elemental iron infusions/injections or a single 1,000 mg elemental iron infusion/injection.

Approval duration: 3 months

C. Iron Deficiency with Heart Failure (must meet all):
1. Diagnosis of iron deficiency confirmed by either of the following (a or b):
   a. Serum ferritin level < 100 ng/mL;
   b. Serum ferritin level between 100 to 300 ng/mL and TSAT < 20%;
2. Member meets all of the following (a, b, c, and d):
   a. Hb < 15 g/dL;
   b. LVEF ≤ 45%;

c. NYHA class II or III;
d. Age ≥ 18 years;

3. Dose does not exceed 1,000 mg elemental iron per infusion/injection.

Approval duration: 12 months

D. Management of Cancer- and Chemotherapy-Induced Anemia (off-label) (must meet all):

1. Diagnosis of iron deficiency, with one of the following iron statuses (a, b, or c):
   a. Absolute iron deficiency confirmed by both (i and ii):
      i. Serum ferritin < 30 ng/mL;
      ii. TSAT < 20%;
   b. Possible functional iron deficiency confirmed by both (i and ii):
      i. Serum ferritin 500-800 ng/mL;
      ii. TSAT < 50%;
   c. Functional iron deficiency with (i, ii, and iii):
      i. Serum ferritin 30-500 ng/mL;
      ii. TSAT < 50%;
      iii. An erythropoietin-stimulating agent (e.g., Epogen®, Procrit®, Aranesp®, Retacrit®) prescribed in combination;
2. Prescribed by or in consultation with an oncologist;
3. Member is prescribed chemotherapy for cancer;
4. Member meets both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed**, or **iron sucrose (generic Venofer)**;
   b. If member has satisfied criterion 4a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Documentation of one of the following laboratory results measured since the last IV iron administration (a or b):
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. Member meets both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of both of the following, unless clinically significant adverse effects are experienced or both are contraindicated: **Ferrlecit** and **iron sucrose (generic Venofer)**;
   b. If member has satisfied criterion 3a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed two 750 mg elemental iron infusions/injections or a single 1,000 mg elemental iron infusion/injection.

Approval duration: 12 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Documentation of one of the following laboratory results measured since the last IV iron administration (a, b, c, d, e, or f):
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;

e. Increased sTfR or sTfR-ferritin index;
f. Increased erythrocyte protoporphyrin level;

3. At the time of the request, member does not have CKD;
4. Member meets both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed**, or **iron sucrose (generic Venofer)**;
   b. If member has satisfied criterion 4a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed two 750 mg elemental iron infusions/injections or a single 1,000 mg elemental iron infusion/injection.

Approval duration: 3 months

C. Iron Deficiency with Heart Failure (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations *(refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Documentation of one of the following laboratory results measured since the last IV iron administration (a or b):
   a. Serum ferritin < 100 ng/mL;
   b. Serum ferritin 100 to 300 ng/mL with transferrin saturation < 20%;
3. If request is for a dose increase, new dose does not exceed a single 1,000 mg elemental iron infusion/injection.

Approval duration: 12 months

D. Management of Cancer- and Chemotherapy-Induced Anemia (off-label) (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Injectafer for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member meets both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: **Ferrlecit**, **Infed**, or **iron sucrose (generic Venofer)**;
   b. If member has satisfied criterion 3a above, failure of **generic Feraheme**, unless contraindicated or clinically significant adverse effects are experienced;

4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hb: hemoglobin
IDA: iron deficiency anemia
LVEF: left ventricular ejection fraction
NYHA: New York Heart Association
TSAT: transferrin saturation
sTfR: soluble transferring receptor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of OTC Oral Iron Formulations*		
Ferrous fumarate (Ferretts, Ferrimin 150)	Varies	
Ferrous gluconate (Ferate)		
Ferrous sulfate (BProtected Pedia Iron, Fe-Vite Iron, Fer-In-Sol, FeroSul, Iron Supplement, Iron Supplement Childrens, One Vite Ferrous Sulfate, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferrix x-150, IFerex 150, NovaFerrum 50, NovaFerrum, NovaFerrum Pediatric Drops, Nu-Iron, Poly-Iron 150)		
Injectable iron agents		
Sodium ferric gluconate (Ferrlecit)	Varies	
Infed (iron dextran)		
iron sucrose (Venofer)		
Ferumoxytol (Feraheme)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Oral formulations include elixirs, liquids, solutions, syrups, capsules, and tablets - including delayed/extended-release tablets.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to Injectafer or any of its inactive components
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IDA	≥ 50 kg (110 lb): two 750 mg doses by IV infusion separated by at least 7 days for a cumulative dose of 1,500 mg per course. In adults: Alternatively, a single-dose treatment course may be administered as 15 mg/kg to a maximum of 1,000 mg. < 50 kg (110 lb): two doses by IV infusion separated by at least 7 days as 15 mg/kg body weight.	Two dose treatment course: 750 mg per dose (up to 1,500 mg) Single dose treatment course: 1,000 mg Treatment may be repeated
Iron deficiency with heart failure and NYHA Class II/III (adults)	< 70 kg (154 lb): Hb < 10 g/dL: 1,000 mg on day 1, then 500 mg on week 6 Hb 10 to 14 g/dL: 1,000 mg on day 1 Hb > 14 to < 15 g/dL: 500 mg on day 1	See dosing regimen

Indication	Dosing Regimen	Maximum Dose
	≥ 70 kg (154 lb): Hb < 10 g/dL: 1,000 mg on day 1, then 1,000 mg on week 6 Hb 10 to 14 g/dL: 1,000 mg on day 1, then 500 mg on week 6 Hb > 14 to < 15 g/dL: 500 mg on day 1 Maintenance dose: 500 mg at 12, 24 and 36 weeks.	

VI. Product Availability

Intravenous solution single-dose vials: 100 mg/2 mL, 750 mg/15 mL, 1,000 mg/20 mL

VII. References

1. Injectafer Prescribing Information. Shirley, NY: American Regent, Inc.; January 2025. Available from https://injectafer.com/. Accessed October 23, 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int*. 2024;105(4S):S117-S314.
3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. Babitt JL, Eisenga MF, Haase VH, et al. Controversies in optimal anemia management: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Conference. Kidney Int. 2021;99(6):1280-1295.
5. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43.
6. Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician.* 2013; 87(2): 98-104. http://www.aafp.org/afp/2013/0115/p98.pdf.
7. DeLoughery TG, Jackson CS, Ko CW, Rockey DC. AGA clinical practice update on management of iron deficiency anemia: expert review. Clin Gastroenterol Hepatol. 2024;22(8):1575-1583.
8. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Wolters Kluwer Health. Updated periodically. Accessed November 25, 2024.
9. Ponikowski P, van Veldhuisen DJ, Comin-Colet J, et al. Beneficial effects of long-term intravenous iron therapy with ferric carboxymaltose in patients with symptomatic heart failure and iron deficiency. Eur Heart J. 2015 Mar 14;36(11):657-68.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(18):e895-e1032.
11. Maddox TM, Januzzi JL Jr, Allen LA, et al. 2024 ACC Expert Consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2024;83(15):1444-1488.
12. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 24, 2025.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1439	Injection, ferric carboxymaltose, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.08.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
1Q 2023 annual review: no significant changes; added updated vial strength of 100 mg/2 mL; FDA-approved age expansion was updated to reflect approval for pediatric patients 1 year of age and older who have either intolerance to oral iron or have had an unsatisfactory response to oral iron; references reviewed and updated.	11.21.22	02.23
Per February SDC, added Commercial line of business; updated initial criteria to require failure of the following with associated age considerations: for IDA and CKD Ferrlecit and Venofer; for IDA without CKD two of Ferrlecit, Infed, or Venofer; additionally, added redirection to Feraheme in a step-wise fashion if member has intolerance or contraindication to all preferred injectable agents.	02.21.23	05.23
RT4: updated FDA Approved Indications(s) section to include iron deficiency with heart failure per updated prescribing information; added to Section I, II, and IV for new indication.	06.19.23	
Per health plan request and SDC, for IDA with and without CKD, added redirections from initial approval criteria to continued therapy.	08.15.23	
Per health plan request and SDC, revised to template redirection language and simplified to remove redirection by age; revised redirection to Feraheme to instead require generic Feraheme.	11.08.23	
1Q 2024 annual review: no significant changes; references reviewed and updated.	11.09.23	02.24
Corrected NYHA class for heart failure indication	03.07.24	
Added criteria for NCCN-supported indication of cancer- and chemotherapy-induced anemia with redirection to preferred iron products.	06.17.24	
1Q 2025 annual review: no significant changes; references reviewed and updated.	11.25.24	02.25
Modified to redirect from brand Venofer to generic per SDC request.	08.21.25	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2026 annual review: no significant changes; added step therapy bypass for IL HIM per IL HB 5395; revised approval durations for iron deficiency associated with CKD, heart failure, and cancer/chemotherapy from 3 months to 12 months; references reviewed and updated.	10.23.25	02.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.