Drug Coverage Policy

Effective Date……09/15/2025
Coverage Policy Number……IP0748
Policy Title…..Injectafer

Iron Replacement – Injectafer

- Injectafer® (ferric carboxymaltose intravenous infusion or slow injection – American Regent)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Injectafer, an iron replacement product, is indicated for the treatment of:[1]

- **Iron deficiency anemia** (IDA), in patients ≥ 1 year of age who have either an intolerance or unsatisfactory response to oral iron.
- **IDA,** in patients ≥ 18 years of age, with **non-dialysis dependent chronic kidney disease** (CKD).
- **Iron deficiency**, in patients ≥ 18 years of age, with **heart failure** and New York Heart Association class II/III to improve exercise capacity.

Guidelines

The Kidney Disease: Improving Global Outcomes clinical practice guideline for anemia in CKD (2025) make various recommendations regarding iron therapy.[2] For patients with CKD and anemia receiving hemodialysis, initiation of IV iron is suggested if transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For patients with CKD and anemia who are not receiving hemodialysis or treated with peritoneal dialysis, initiation of oral or IV iron is suggested if TSAT is < 40% and ferritin < 100 ng/mL or if TSAT < 25% with ferritin ≥ 100 ng/mL and < 300 ng/ml. For patients with CKD and profound iron deficiency (TSAT < 20% and ferritin < 30 ng/mL) but no anemia, consider treatment with oral or IV iron. Additional practice points are noted such as a switch from oral to IV iron if there is an insufficient effect of an optimal oral regimen after 1 to 3 months. KDIGO also notes the choice between different formulations of IV iron should be guided by individual considerations and recommended dosing schedules.

The National Comprehensive Cancer Network guidelines on hematopoietic growth factors (version 1.2025 – October 11, 2024) discuss the management of cancer- and chemotherapy-induced anemia.[3] Treatment for iron deficiency is guided by iron status which is defined in the guidelines as: absolute iron deficiency, functional iron deficiency, possible functional iron deficiency, or no iron deficiency and use in combination with erythropoiesis-stimulating agents. IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%), functional iron deficiency (ferritin = 30 to 500 ng/mL and TSAT < 50%) in patients who are also receiving an ESA, and for select patients with possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%). All recommendations are category 2A for each product.

The American College of Cardiology/American Heart Association guideline for the management of heart failure (2022) states that in patients with heart failure with reduced ejection fraction (left ventricular ejection fraction ≤ 40%), absolute iron deficiency (ferritin < 100 ng/mL) or functional iron deficiency (ferritin = 100 to 300 mg/mL if TSAT is < 20%), and with or without anemia, IV iron replacement is reasonable to improve functional status and quality of life (2a recommendation).[4]

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for benefit coverage of Injectafer. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Injectafer as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Injectafer to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Injectafer is considered medically necessary when ONE of the following is met:

FDA-Approved Indications

1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are NOT on Dialysis**. Approve for 1 year if the patient meets **ALL** of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND

B) The medication is prescribed by or in consultation with a nephrologist or hematologist.
C) Preferred product criteria is met for the product(s) as listed in the below table(s)

Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

2. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets **ALL** of the following (A and B):
   A) Patient is ≥ 1 year of age; AND
   B) Patient meets ONE of the following (i, ii, iii, or iv):
      i. Patient meets BOTH of the following (a and b):
         a) Patient has tried oral iron supplementation; AND
         b) According to the prescriber, oral iron supplementation was ineffective or intolerable; OR
      ii. According to the prescriber, patient has a condition that will interfere with oral iron absorption; OR
      Note: Examples of conditions that may interfere with oral iron absorption may include inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
      iii. Patient is currently receiving an erythropoiesis-stimulating agent; OR
      Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product.
      iv. The medication is being requested for cancer- or chemotherapy-related anemia.

   Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

3. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the patient meets **ALL** of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Injectafer is being prescribed by or in consultation with a cardiologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1500 mg given intravenously per 30 days.

Other Uses with Supportive Evidence

4. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis**. Approve for 3 years.

Employer Plans:

Product	Criteria
Injectafer (ferric carboxymaltose)	**Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on dialysis.** Patient meets **ONE** of the following (1, 2, or 3): 1. Patient has tried at least one of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR 2. Patient is < 2 years of age; OR 3. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.

Individual and Family Plans:

Product	Criteria
Injectafer (ferric carboxymaltose)	**Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are <u>not</u> on dialysis.** Patient meets **ONE** of the following (1, 2, or 3): 1. Patient has tried at least <u>one</u> of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR 2. Patient is < 2 years of age; OR 3. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Injectafer for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1439	Injection, ferric carboxymaltose, 1 mg

References

1. Injectafer® [prescribing information]. Shirley, NY: American Regent; May 2023.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. 2025 KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease (*November 2024 Public Review Draft*). Available at: https://kdigo.org/guidelines/anemia-in-ckd/. Accessed on January 8, 2025
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org Accessed on January 7, 2025.

4. 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 [published correction appears in *J Am Coll Cardiol*. 2023 Apr 18;81(15):1551]. *J Am Coll Cardiol*. 2022;79(17):e263-e421.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	09/15/2025

The policy effective date is in force until updated or retired.