



## Drug Coverage Policy

Effective Date .....4/1/2026

Coverage Policy Number.....IP0748

Policy Title.....Injectafer

# Iron Replacement – Injectafer

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

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### **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.*

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### **OVERVIEW**

Injectafer, an intravenous iron replacement product, is indicated for the treatment of:<sup>1</sup>

- **Iron deficiency anemia (IDA)**, in adult and pediatric patients ≥ 1 year of age who have either an intolerance or an unsatisfactory response to oral iron.

- **IDA**, in patients  $\geq 18$  years of age, with **non-dialysis dependent chronic kidney disease** (CKD).
- **Iron deficiency**, in patients  $\geq 18$  years of age, with **heart failure** and New York Heart Association class II/III to improve exercise capacity.

### Dosing Information

Injectafer is administered by intravenous (IV) infusion or slow injection, and treatment may be repeated if iron deficiency remains persistent or recurring.<sup>1</sup> For treatment of IDA, in patients weighing  $\geq 50$  kg, the recommended dose is up to 750 mg per dose with a total cumulative dose not to exceed 1500 mg per treatment course. For patients weighing  $< 50$  kg, the recommended dose is 15 mg/kg in two doses separated by at least 7 days per course. For adult patients weighing  $\geq 50$  kg, an alternative dose of 15 mg/kg body weight up to a maximum of 1,000 mg may be administered IV as a single dose per course.

See Table 1 for recommended dosage of Injectafer for the treatment of iron deficiency with heart failure.

**Table 1. Recommended Dosage of Injectafer in Patients with Iron Deficiency with Heart Failure.<sup>1</sup>**

	Weight < 70 kg			Weight $\geq 70$ kg		
	Hb < 10 g/dL	Hb 10-14 g/dL	Hb >14 to <15 g/dL*	Hb < 10 g/dL	Hb 10-14 g/dL	Hb >14 to < 15 g/dL*
Day 1	1,000 mg	1,000 mg	500 mg	1,000 mg	1,000 mg	500 mg
Week 6	500 mg	No dose	No dose	1,000 mg	500 mg	No dose
Beyond Week 6	Administer a <b>maintenance dose</b> of 500 mg at 12, 24 and 36 weeks if serum ferritin < 100 ng/mL or serum ferritin 100 to 300 ng/mL with transferrin saturation < 20%.*					

Hb – hemoglobin; \*There are no data available to guide dosing beyond 36 weeks or with Hb  $\geq 15$  g/dL.

### Guidelines

#### Anemia in CKD

The Kidney Disease: Improving Global Outcomes clinical practice guideline for anemia in CKD (2025) make various recommendations regarding iron therapy.<sup>2</sup> For patients with CKD and anemia receiving hemodialysis, initiation of IV iron is suggested if transferrin saturation (TSAT) is  $\leq 30\%$  and ferritin is  $\leq 500$  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  $\geq 100$  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.

#### Cancer-Related Anemia

The National Comprehensive Cancer Network guidelines on hematopoietic growth factors (version 3.2026 – December 5, 2025) discuss the management of cancer- and chemotherapy-induced anemia.<sup>3</sup> 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 (ESAs). IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin  $< 30$  ng/mL and TSAT  $< 20\%$ ) and possible functional iron deficiency (ferritin  $> 500$ -800 ng/mL and TSAT  $< 50\%$ ) in selected patients (with the goal of avoiding allogeneic transfusion). IV iron therapy is also considered an option in combination with ESAs for the treatment of functional iron deficiency (ferritin 30 to 500

ng/mL and TSAT < 50%) in patients receiving myelosuppressive chemotherapy without curative intent and absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%) in patients who do not experience an increase in hemoglobin after four weeks of IV or oral iron supplementation. All recommendations are category 2A for each product.

#### *Heart Failure*

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  $\leq$  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).<sup>4</sup>

#### **Safety**

Injectafer has a unique warning and precaution regarding symptomatic hypophosphatemia.<sup>1</sup> Symptomatic hypophosphatemia with serious outcomes including osteomalacia and fractures requiring clinical intervention has been reported in patients treated with Injectafer in the post-marketing setting.

## 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  $\geq$  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  $\geq$  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  $\geq$  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
<b>Injectafer</b> (ferric carboxymaltose)	<b>Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are <u>not</u> on dialysis.</b> Patient meets <b>ONE</b> of the following (1, 2, or 3): <ol style="list-style-type: none"> <li>1. Patient has tried at least <u>one</u> of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR</li> <li>2. Patient is &lt; 2 years of age; OR</li> <li>3. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.</li> </ol>

**Individual and Family Plans:**

Product	Criteria
<b>Injectafer</b> (ferric carboxymaltose)	<b>Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are <u>not</u> on dialysis.</b> Patient meets <b>ONE</b> of the following (1, 2, or 3): <ol style="list-style-type: none"> <li>1. Patient has tried at least <u>one</u> of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR</li> <li>2. Patient is &lt; 2 years of age; OR</li> <li>3. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.</li> </ol>

**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:**

<b>HCPCS Codes</b>	<b>Description</b>
J1439	Injection, ferric carboxymaltose, 1 mg

## References

1. Injectafer® [prescribing information]. Shirley, NY: American Regent; January 2025.
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 December 15, 2025.
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 3.2026 – December 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 16, 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

<b>Type of Revision</b>	<b>Summary of Changes</b>	<b>Date</b>
New	New policy.	09/15/2025
Annual Revision	No criteria changes.	4/1/2026

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

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