Corporate Medical Policy: Intravenous Iron Replacement Therapy **"Notification"** **POLICY EFFECTIVE OCTOBER 1, 2026**

Restricted Product(s):

- ferric carboxymaltose (Injectafer®) intravenous infusion for administration by a healthcare professional
- ferric derisomaltose (Monoferric®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- Ferric carboxymaltose (Injectafer®)
  - For the treatment of iron deficiency anemia (IDA) in adults and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron
  - For the treatment of iron deficiency anemia (IDA) in adults who have non-dialysis dependent chronic kidney disease
  - For the treatment of iron deficiency in adults with heart failure and New York Heart Association (NYHA) class II/III to improve exercise capacity
- Ferric derisomaltose (Monoferric®)
  - For the treatment of iron deficiency anemia (IDA) in adults who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease

NOTE: This policy addresses ferric carboxymaltose (Injectafer) and ferric derisomaltose (Monoferric) intravenous iron therapies only.

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. ONE of the following:
   a. The requested agent is ferric carboxymaltose (Injectafer), and ONE of the following:
      i. The patient has a diagnosis of iron deficiency anemia (IDA) without chronic kidney disease (CKD); **OR**
      ii. The patient has a diagnosis of IDA and non-dialysis dependent CKD; **OR**
      iii. The patient has a diagnosis of iron deficiency with New York Heart Association (NYHA) class II/III heart failure; **OR**
   b. The requested agent is ferric derisomaltose (Monoferric), and BOTH of the following:
      i. The patient is 18 years of age or older; **AND**
      ii. ONE of the following:
         1. The patient has a diagnosis of iron deficiency anemia (IDA) without chronic kidney disease (CKD); **OR**

2. The patient has a diagnosis of IDA and non-dialysis dependent CKD; **AND**

2. ONE of the following:
    a. The patient has tried and had an inadequate response to oral iron therapy used for at least 3 months **[medical record documentation required]**; **OR**
    b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to oral iron therapy **[medical record documentation required]**; **OR**
    c. Documentation has been provided supporting the use of the requested agent over oral iron therapy **[medical record documentation required]**; **AND**
3. ONE of the following:
    a. The patient is less than 6 years of age AND ONE of the following:
        i. The patient has tried and had an inadequate response to ONE of the following **[medical record documentation required]**:
            1. Iron sucrose (Venofer®); **OR**
            2. Iron dextran (INFeD®); **OR**
        ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to iron sucrose (Venofer) AND iron dextran (INFeD) that is not expected to occur with the requested agent **[medical record documentation required]**; **OR**
    b. The patient is at least 6 years of age and less than 18 years of age AND ONE of the following:
        i. The patient has tried and had an inadequate response to ONE of the following **[medical record documentation required]**:
            1. Sodium ferric gluconate complex in sucrose (Ferrlecit®); **OR**
            2. Iron sucrose (Venofer®); **OR**
            3. Iron dextran (INFeD®); **OR**
        ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to sodium ferric gluconate complex in sucrose (Ferrlecit), iron sucrose (Venofer), AND iron dextran (INFeD) that is not expected to occur with the requested agent **[medical record documentation required]**; **OR**
    c. The patient is 18 years of age or older AND ONE of the following:
        i. The patient has tried and had an inadequate response to TWO of the following **[medical record documentation required]**:
            1. Sodium ferric gluconate complex in sucrose (Ferrlecit®); **OR**
            2. Iron sucrose (Venofer®); **OR**
            3. Iron dextran (INFeD®); **OR**
            4. Ferumoxytol (Feraheme®); **OR**
        ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to sodium ferric gluconate complex in sucrose (Ferrlecit), iron sucrose (Venofer), iron dextran (INFeD), AND ferumoxytol (Feraheme) that is not expected to occur with the requested agent **[medical record documentation required]**; **AND**
4. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**

5. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

   Duration of Approval:
   IDA with or without CKD: 30 days (one treatment course)
   Iron deficiency with heart failure: 60 days

Continuation Criteria for Approval:

1. ONE of the following:
   a. The requested agent is ferric carboxymaltose (Injectafer) AND the patient has a diagnosis of iron deficiency with New York Heart Association (NYHA) class II/III heart failure; **AND**
      i. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
      ii. The patient would have met initial criteria for approval at the time they started therapy; **OR**
   b. For all other requests, **please refer to initial criteria for approval**; **AND**
2. The patient has been receiving treatment with ferric carboxymaltose (Injectafer) for the requested indication and requires maintenance dosing, as demonstrated by ONE of the following:
   a. Serum ferritin less than 100 ng/mL; **OR**
   b. Serum ferritin 100 to 300 ng/mL AND transferrin saturation (TSAT) less than 20%; **AND**
3. The patient's hemoglobin level is less than 15 g/dL; **AND**
4. The patient has NOT received and will NOT exceed more than 36 weeks of treatment with the requested agent; **AND**
5. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
6. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

   Duration of Approval: 180 days (6 months)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
ferric carboxymaltose (Injectafer®) intravenous (IV) infusion	IDA in adults 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 adults who have non-dialysis dependent chronic kidney disease Iron deficiency in adults with heart failure and NYHA class II/III	**IDA:** • Weight ≥ 50 kg: 750 mg IV in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course; alternative dosing: 15 mg/kg up to a max of 1,000 mg as a single-dose treatment course • Weight < 50 kg: 15 mg/kg IV in two doses separated by at least 7 days for a cumulative dose not to exceed 1,500 mg of iron per course • May be repeated if IDA reoccurs **Iron deficiency with heart failure:** • Day 1: ○ Hb ≤ 14 g/dL: 1,000 mg IV ○ Hb > 14 to < 15 g/dL: 500 mg IV • Week 6: ○ Hb < 10 g/dL: ▪ Weight < 70 kg: 500 mg IV ▪ Weight ≥ 70 kg: 1,000 mg IV ○ Hb 10 to 14 g/dL ▪ Weight < 70 kg: No dose ▪ Weight ≥ 70 kg: 500 mg IV ○ Hb > 14 to < 15: No dose • Maintenance dose: 500 mg IV at 12, 24, and 36 weeks if serum ferritin < 100 ng/mL or serum	J1439	**IDA:** 1,500 **Iron deficiency in heart failure:** Initial: 2,000 Continuation: 1,500

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		ferritin 100-300 ng/mL with transferrin saturation (TSAT) < 20% • There is no data available to guide dosing beyond 36 weeks or with hemoglobin (Hb) ≥ 15 g/dL		
ferric derisomaltose (Monoferric®) intravenous (IV) infusion	IDA in adults who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease	• Patients weighing ≥ 50 kg: 1,000 mg IV over at least 20 minutes as a single dose • Patients weighing < 50 kg: 20 mg/kg IV over at least 20 minutes as a single dose • May be repeated if IDA reoccurs	J1437	100

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:

   i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
   ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
g. Requirement of a change in the requested restricted product formulation; **AND**

3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Short MW, Domagalski JE. Iron deficiency anemia: evaluation and management. *Am Fam Physician*. 2013 Jan 15;87(2):98-104.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

October 2026: Criteria change: Added product-specific diagnoses within criteria and age limitation for Monoferric according to FDA labeled indications. For Injectafer for treatment of iron deficiency with heart failure, extended duration of approval for initial treatment to 60 days and added continuation criteria for this indication to allow for maintenance treatment, not exceeding more than 36 weeks, according to FDA labeled dosing. Adjusted Injectafer maximum units for treatment of iron deficiency with heart failure for clarity according to label. Added Site of Care medical necessity criteria. Other formatting changes made throughout policy and dosing reference table for clarity. **Policy notification given 8/3/2026 for effective date 10/1/2026**.
October 2023: Criteria change: Added newly approved Injectafer indication for iron deficiency in adults with heart failure and NYHA class II/III, and added associated dosing in FDA Label Reference table. Updated trial and failure requirements by age according to product specific FDA labels for clarity.
April 2023: Criteria change: Removed Feraheme from the restricted product list. Restructured trial and failure requirements by age and added requirement of trial and failure of two products (i.e., Ferrlecit, Venofer, INFeD, Feraheme) for adults. **Policy notification given 2/1/2023 for effective date 4/1/2023**.
February 2022: Criteria update: Added pediatric Injectafer indication.
October 2021: Criteria change: Changed trial and failure requirement from all preferred products (Ferrlecit, Venofer, and Infed) to one preferred product (Ferrlecit, Venofer, or Infed).
October 2021: Original medical policy criteria issued. **Policy notification given 7/1/2021 for effective date 10/1/2021**.