



## RX.PA.044.MPC IV and Injectable Iron Products

The purpose of this policy is to define the prior authorization process for Injectafer® (ferric carboxymaltose), Monoferric® (ferric derisomaltose), Infed® (iron dextran), Venofer® (iron sucrose), Ferrlecit® (sodium ferric gluconate), Feraheme® (ferumoxytol)

### PROCEDURE

#### Initial Authorization Criteria:

#### A. All requests for IV and injectable iron medications must meet the following criteria:

- Requests for Injectafer® (ferric carboxymaltose), Monoferric® (ferric derisomaltose), Infed® (iron dextran), Venofer® (iron sucrose), Ferrlecit® (sodium ferric gluconate), Feraheme® (ferumoxytol) are subject to the preferred medical medication list.
- The infusion setting impacts which IV/injectable iron products are considered preferred.
  - *Regulated settings:* hospital and related healthcare systems
  - *Non-regulated settings:* non-hospital outpatient infusion centers, physician offices, ambulatory infusion centers and home infusion services

Non-Regulated Settings	
Preferred	Non-Preferred
Feraheme® (ferumoxytol) Ferrlecit® (sodium ferric gluconate) Infed® (iron dextran) Venofer® (iron sucrose)	Injectafer® (ferric carboxymaltose) Monoferric® (ferric derisomaltose)
Regulated Settings	
Preferred	Non-Preferred
Ferrlecit® (sodium ferric gluconate) Infed® (iron dextran) Venofer® (iron sucrose)	Feraheme® (ferumoxytol) Injectafer® (ferric carboxymaltose) Monoferric® (ferric derisomaltose)

- For requests for non-preferred products, must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must have documented trial and failure of at least 1 month of oral iron therapy
  - Defined as Hgb did not increase by 1 point (requires documentation of immediate pre and post-trial labs)

**OR**

- Must have documented trial and failure of 3 months of oral iron therapy
  - Defined as iron level did not increase to produce a significant result
- Intolerance to oral iron therapy

**OR**

- Oral iron therapy would not be appropriate due to one of the following reasons:
  - Hemoglobin (Hgb) < 7 g/dL
  - TSAT < 12%
    - Confirmed via calculation (TSAT = Serum Iron (FE) µg/dL / Total Iron-Binding Capacity (TIBC) µg/dL)
  - Severe and ongoing blood loss
  - Intractable bleeding disorders. Examples include, but not limited to:
    - Colonic telangiectasias/angiodysplasia
    - Small bowel telangiectasias
  - Physiologic or anatomic condition that would impact absorption of oral iron therapy. Examples include, but not limited to:
    - Inflammatory bowel disease (Crohn's disease, Ulcerative Colitis)
    - Bariatric surgery or gastrectomy
    - Celiac Disease
    - Duodenal Ulcers
  - 3rd trimester pregnancy with a high-risk hemorrhagic state, such as placenta previa, Hgb < 8 g/dL, Vasa previa, or placenta accreta
    - Note: IV Iron is not recommended in the 1<sup>st</sup> trimester
  - Concurrent use of required medications that may significantly limit oral iron absorption
  - Note: For cases indicating GI intolerance to oral iron, must include documentation that the member has tried and failed a reduced dosing schedule (every other day, MWF, etc)

**B. Diagnosis of iron deficiency anemia without chronic kidney disease:**

- Must have the following supporting laboratory documentation within 60 days of request (a and b)
  - a) Measured ferritin level is < 30 mcg/L; **AND**
  - b) Transferrin saturation (TSAT) < 20%
    - Confirmed via calculation (TSAT = Serum Iron (FE) µg/dL / Total Iron-Binding Capacity (TIBC) µg/dL)

**C. Diagnosis of iron deficiency anemia with chronic kidney disease:**

- Must have the following supporting laboratory documentation within 60 days of request:
  - Ferritin ≤ 500 ng/mL (≤ 500 mg/L)

- Transferrin saturation (TSAT)  $\leq$  30%
  - Does not apply to patients on hemodialysis receiving erythropoiesis stimulating medications
  - Confirmed via calculation (TSAT = Serum Iron (FE)  $\mu$ g/dL / Total Iron-Binding Capacity (TIBC)  $\mu$ g/dL)
- Note: Injectafer is not indicated for members on dialysis

**D. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

- **Note: Requests for dosages exceeding limits listed below will be subject to prior authorization and will require medical justification, including iron repletion calculations.**

	Products	Dosing
Preferred	Ferlecit® (sodium ferric gluconate)	<ul style="list-style-type: none"> <li>• 125-250mg per treatment</li> <li>• 1,000mg cumulative dose</li> </ul>
	Venofer® (iron sucrose)	<ul style="list-style-type: none"> <li>• 100-300mg per treatment</li> <li>• 1,000mg cumulative dose</li> </ul>
	Infed® (iron dextran)	<ul style="list-style-type: none"> <li>• 1,000mg cumulative dose</li> </ul>
Non-preferred	Injectafer® (ferric carboxymaltose)	<ul style="list-style-type: none"> <li>• 750mg per treatment</li> <li>• 1,500mg cumulative dose</li> </ul>
	Monoferric® (ferric derisomaltose)	<ul style="list-style-type: none"> <li>• 2,000mg cumulative dose</li> </ul>
	Feraheme® (ferumoxytol)	<ul style="list-style-type: none"> <li>• 510mg per treatment</li> <li>• 1,020mg cumulative dose</li> </ul>

**E. IV and Injectable Iron products will be considered investigational or experimental for any other use and will not be covered.**

**Reauthorization Criteria:**

**Note: Requests for reauthorization of non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products**

**1. Diagnosis of iron deficiency anemia without chronic kidney disease:**

- Must have the following supporting laboratory documentation:
  - Normalization of hemoglobin levels (3 months following last IV iron treatment)
    - 13.5 to 17.5 g/dL for males
    - 12.0 to 15.5 g/dL for females
    - Note: documentation of medical necessity and treatment plan required from provider if member fails to reach normal hemoglobin levels

- Iron levels (3 months following last dosage)
  - Measured ferritin level is < 30 mcg/L
OR
  - Transferrin saturation (TSAT) < 20%

Confirmed via calculation (TSAT = Serum Iron (FE) µg/dL /Total Iron- Binding Capacity (TIBC) µg/dL)

- Documentation of an additional trial to transition the patient to oral iron therapy unless intolerant. If member is intolerant, must provide justification for the inability to retrial oral iron therapy.
- Documentation that the member has been evaluated for underlying IDA complicating factors and referred to appropriate specialist when applicable following initial iron treatment cycle.

## 2. Diagnosis of iron deficiency anemia with chronic kidney disease:

- Must have the following supporting laboratory documentation (3 months following last IV iron treatment):
  - Improved Hemoglobin (Hgb) from baseline (if Hgb does not improve from baseline, must provide documentation of medical evaluation for failure to improve)
  - AND
  - Transferrin saturation (TSAT) ≤ 30%
  - AND
  - Ferritin ≤ 500 ng/mL (≤ 500 mg/L)
- Documentation of an additional trial to transition the patient to oral iron therapy unless intolerant. If member is intolerant, must provide justification for the inability to retrial oral iron therapy.

### **Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	IDA without CKD: 3 months IDA with CKD: 6 months

### **Codes:**

Code	Description
J1437	Injection, ferric derisomaltose (Monoferric), 10 mg
J1439	Injection, ferric carboxymaltose (Injectafer), 1 mg
J1750	Injection, iron dextran (Infed), 50 mg
J1756	Injection, iron sucrose (Venofer), 1 mg
J2916	Injection, sodium ferric gluconate (Ferrlecit), 12.5 mg
Q0138	Injection, ferumoxytol (Feraheme), 1 mg
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

## REFERENCES

1. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; April 2021.
2. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; July 2020.
3. Infed [package insert]. Madison, NJ: Allergan, Inc.; September 2020.
4. Venofer [package insert]. Shirley, NY: American Regent, Inc.; September 2020.
5. Ferlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S., LLC.; December 2020.
6. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; September 2020.

## REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Update to preferred vs non-preferred list to include site of service requirements</i>	<i>08/2025</i>
<i>Removal of site of service requirement</i>	<i>03/2025</i>
<i>Addition of exceptions to trial of oral iron therapy, removed serum iron requirements and updated TSAT requirement</i>	<i>01/2025</i>
<i>Update to oral iron treatment duration requirement</i>	<i>11/2024</i>
<i>Annual review</i>	<i>02/2024</i>
<i>Addition of TSAT calculation on the initial review to confirm lab value</i>	<i>11/2023</i>
<i>Selected Revision</i> <i>Initial criteria to require laboratory documentation within 60 days of request</i> <i>Addition of site of service policy requirements</i>	<i>04/2023</i>
<i>Annual review</i>	<i>02/2023</i>
<i>Addition of transferrin saturation (TSAT) level to the non-CKD anemia initial criteria</i>	<i>11/2022</i>
<i>Removal of TIBC requirements for non-CKD anemia</i>	<i>10/2022</i>
<i>Update to the reauthorization criteria for IDA without chronic kidney disease. Update to reauthorization periods based on indication.</i>	<i>07/2022</i>
<i>Addition of maximum dosing limits</i>	<i>06/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>P&amp;T Review</i>	<i>11/2021</i>

<i>Addition of Q0139</i>	<i>09/2021</i>
<i>Policy Creation</i>	<i>09/2021</i>