

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

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

**Site of Service**

Medication(s) included in this criteria are subject to review under policy RX.PA.070.MPC: [Site of Service - Outpatient Infusion/Injection Services](#)

**PROCEDURE**

**Initial Authorization Criteria:**

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

- Requests for Injectafer<sup>®</sup> (ferric carboxymaltose), Monoferric<sup>®</sup> (ferric derisomaltose), Infed<sup>®</sup> (iron dextran), Venofer<sup>®</sup> (iron sucrose), Ferrlecit<sup>®</sup> (sodium ferric gluconate), Feraheme<sup>®</sup> (ferumoxytol) are subject to the preferred medical medication list.

	Products
Preferred	<ul style="list-style-type: none"> <li>• <b>Ferrlecit<sup>®</sup> (sodium ferric gluconate)</b></li> <li>• <b>Venoferr<sup>®</sup> (iron sucrose)</b></li> <li>• <b>Infed<sup>®</sup> (iron dextran)</b></li> </ul>
Non-preferred	<ul style="list-style-type: none"> <li>• <b>Injectafer<sup>®</sup> (ferric carboxymaltose)</b></li> <li>• <b>Monoferric<sup>®</sup> (ferric derisomaltose)</b></li> <li>• <b>Feraheme<sup>®</sup> (ferumoxytol)</b></li> </ul>

- 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 3-6 months of oral iron therapy **OR** 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)  $\mu\text{g/dL}$

- Severe and ongoing blood loss
- Physiologic or anatomic condition that would impact absorption of oral iron therapy. Examples include, but not limited to:
  - Inflammatory bowel disease
  - Bariatric surgery or gastrectomy
- 3<sup>rd</sup> trimester pregnancy with a high-risk hemorrhagic state, such as placenta previa, or Hgb < 8 g/dL
- 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 or c)
  - a) Measured ferritin level is < 30 mcg/L; **AND**
  - b) Measured serum iron level and transferrin saturation level are below the lower range of normal

**OR**

- c) Transferrin saturation (TSAT) < 12%
  - Confirmed via calculation (TSAT = Serum Iron (FE)  $\mu\text{g/dL}$  / Total Iron-Binding Capacity (TIBC)  $\mu\text{g/dL}$ )

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

- Must have the following supporting laboratory documentation within 60 days of request:
  - Ferritin  $\leq 500$  ng/mL ( $\leq 500$  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)  $\mu\text{g/dL}$  / Total Iron-Binding Capacity (TIBC)  $\mu\text{g/dL}$ )
- 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	Ferrlecit® (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 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
    - Measured serum iron level and transferrin saturation level are below the lower range of normal
- Documentation of concomitant condition preventing use of oral iron therapy, failure to transition patient to oral iron therapy or justification for not administering an additional trial of 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
- AND
- Transferrin saturation (TSAT) ≤ 30%
- AND
- Ferritin ≤ 500 ng/mL (≤ 500 mg/L)
- Documentation of concomitant condition preventing use of oral iron therapy, failure to transition patient to oral iron therapy or justification for not administering an additional trial of 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. Ferrlecit [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>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 Initial criteria to require laboratory documentation within 60 days of request 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>