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.

	Products
Preferred	• **Ferrlecit® (sodium ferric gluconate)** • **Venofer® (iron sucrose)** • **Infed® (iron dextran)**
Non-preferred	• **Injectafer® (ferric carboxymaltose)** • **Monoferric® (ferric derisomaltose)** • **Feraheme® (ferumoxytol)**

- 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%
    - 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

- 3rd 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
  - Measured ferritin level is < 30 mcg/L; **AND**
  - Measured serum iron level and transferrin saturation level are below the lower range of normal
    OR
  - Transferrin saturation (TSAT) < 12%

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

- Must have the following supporting laboratory documentation:
  - Ferritin ≤ 500 ng/mL (≤ 500 mg/L)
  - Transferrin saturation (TSAT) ≤ 30%
    - Does not apply to patients on hemodialysis receiving erythropoiesis stimulating medications
- 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)	• 125-250mg per treatment • 1,000mg cumulative dose
	Venofer® (iron sucrose)	• 100-300mg per treatment • 1,000mg cumulative dose
	Infed® (iron dextran)	• 1,000mg cumulative dose
Non-preferred	Injectafer® (ferric carboxymaltose)	• 750mg per treatment • 1,500mg cumulative dose
	Monoferric® (ferric derisomaltose)	• 2,000mg cumulative dose
	Feraheme® (ferumoxytol)	• 510mg per treatment • 1,020mg cumulative dose

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 dosage)
    - 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:
  - 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
Annual review	*02/2023*
Addition of transferrin saturation (TSAT) level to the non-CKD anemia initial criteria	*11/2022*
Removal of TIBC requirements for non-CKD anemia	*10/2022*
Update to the reauthorization criteria for IDA without chronic kidney disease. Update to reauthorization periods based on indication.	*07/2022*
Addition of maximum dosing limits	*06/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2021*
Addition of Q0139	*09/2021*

Policy Creation	*09/2021*