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 1st 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; **OR**

    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) ≤ 30%
  - Does not apply to patients on hemodialysis receiving erythropoiesis stimulating medications
  - Confirmed via calculation (TSAT = Serum Iron (FE) µg/dL / Total Iron-Binding Capacity (TIBC) µg/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)	• 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.

<u>Reauthorization Criteria:</u>

- 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)

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:
  - Hemoglobin levels from baseline (3 months following last IV iron treatment)
  - 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

Length of Authorization (if above criteria met)	
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
Update to include preferred vs non-preferred products under the continuation of therapy pathway	*09/2026*
Update to IDA non-CKD requirement to make TSAT and Ferritin labs an either or requirement. Removal of Hgb thresholds in the COT section for IDA non-CKD	*06/2026*
Annual Review	*02/2026*
Update to preferred vs non-preferred list to include site of service requirements	*08/2025*
Removal of site of service requirement	*03/2025*
Addition of exceptions to trial of oral iron therapy, removed serum iron requirements and updated TSAT requirement	*01/2025*
Update to oral iron treatment duration requirement	*11/2024*

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Update to include preferred vs non-preferred products under the continuation of therapy pathway	*09/2026*
Annual review	*02/2024*
Addition of TSAT calculation on the initial review to confirm lab value	*11/2023*
Selected Revision *Initial criteria to require laboratory documentation within 60 days of request* *Addition of site of service policy requirements*	*04/2023*
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*