

The Oncology Institute				
Intravenous Iro				
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TOI-IV Iron	Effective Date: 09-01-2025			

Overview:

Iron deficiency anemia is a very common hematologic condition affecting individuals across the lifespan and in a variety of settings. There are currently no authoritative guidelines for hematologists for the treatment of iron deficiency anemia which can contribute to wide variation in management. This policy outlines medical necessity criteria for reviewing requests for the following intravenous iron replacement therapies.

Feraheme®

• Ferrlecit®

Infed®

Injectafer®

Monoferric[®]

Venofer[®]

Medical Necessity Criteria:

Intravenous iron replacement therapies are considered medically necessary for iron deficiency anemia when the individual meets ALL the following criteria:

- 1. Hemoglobin ≤11 g/dL or ≥2 g/dL below baseline*, AND
- 2. Ferritin <30 ng/mL AND transferrin saturation (TSAT) <20%*, AND
- 3. Failure** or intolerance to oral iron therapy, **OR ONE** of the following:
 - i. Patient has severe iron deficiency in late-stage pregnancy.
 - *ii.* Patient has impaired absorption due to prior gastric surgery or disorder of the gastrointestinal tract (e.g. celiac disease, inflammatory bowel disease)
 - iii. Blood loss exceeds the ability to replete iron orally.

^{*}Submitted laboratory values must be within past 60 days of request

^{**} Failure defined as inadequate response after at least 3 months of therapy



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Billing:

Drug Name	HCPCS Code	Description
Feraheme®	Q0138	Injection, ferumoxytol, for treatment of iron deficiency
		anemia, 1 mg (non-esrd use)
Ferrlecit®	J2916	Injection, sodium ferric gluconate
Infed®	J1750	Injection, iron dextran
Injectafer®	J1439	Injection, ferric carboxymaltose, 1 mg
Monoferric®	J1437	Injection, ferric derisomaltose, 10 mg
Venofer®	J1756	Injection, iron sucrose, 1 mg

References:

- 1. Feraheme [package insert]. Waltham, MA: Amag Pharmaceuticals, Inc.; Revised June 2022
- 2. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Avantis U.S. LLC; Revised March 2022
- 3. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; Revised August 2024
- 4. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; Revised Jan 2025
- 5. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; Revised August 2024
- 6. Venofer [package insert]. Shorley, NY: American Regent, Inc.; Revised August 2024
- 7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hematopoietic Growth Factors [Version 1.2025].

Revision History:

V1.0 No Preceding Documents (Prepared by Rama Al Ghannam, PharmD, BCOP)

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V1.0	9/1/2025	Reviewed by Jeffrey Langsam, DO and Richy Agajanian, MD