



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Iron – Injectable Step Therapy Edit
<b>First Implementation Date:</b>	November 19, 2020
<b>Revised Date:</b>	October 26, 2023
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of injectable iron therapy

**Why Issue Selected:** Iron deficiency anemia is the most common nutritional disorder in the world, accounting for approximately 50% of anemia cases. It is estimated that there are 8–9 million patients in the U.S. who suffer from iron deficiency anemia. Also, the most common reversible cause of chronic anemia or worsening anemia in patients with chronic kidney disease (CKD), other than anemia related directly to CKD, is iron deficiency anemia. Once discovered, the underlying cause of anemia should be treated. Oral iron therapy is used initially to replenish the body’s iron stores; injectable iron therapy may be used in patients who cannot tolerate or absorb the oral agents. Due to the high cost, MO HealthNet will impose clinical criteria to ensure appropriate utilization of injectable iron therapies.

Program-Specific Information:	Date Range FFS 4-1-2022 to 3-31-2023			
	Drug	Claims	Spend	Avg Spend per Claim
	FERAHEME 510 MG/17 ML VIAL	13	\$ 4,620.25	\$ 355.40
	FERRLECIT 62.5 MG/5 ML VIAL	1,967	\$ 22,150.62	\$ 11.26
	FERRLECIT GENERIC 62.5 MG/5	941	\$ 12,918.21	\$ 13.73
	INFED 100 MG/2 ML VIAL	558	\$ 118,857.54	\$ 213.01
	INJECTAFER 100 MG/2 ML VIAL	0	-	-
	INJECTAFER 750 MG/15 ML VIAL	89	\$ 67,375.16	\$ 757.02
	INJECTAFER 1,000 MG/20 ML VIAL	0	-	-
	MONOFERRIC 1,000 MG/10 ML VIAL	5	\$ 12,867.77	\$ 2,573.55
	TRIFERIC 27.2 MG/5 ML AMP	0	-	-
	TRIFERIC 272 MG PWD PKT	0	-	-
	VENOFER 100 MG/5 ML VIAL	15,179	\$ 908,968.89	\$ 59.88
	VENOFER 200 MG/10 ML VIAL	838	\$ 55,564.72	\$ 67.11
	VENOFER 50 MG/2.5 ML VIAL	7,315	\$ 133,208.30	\$ 18.21

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Step Therapy Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Injectable iron therapy
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Claim for Ferrlecit, Infed, Triferic, or Venofer **OR**
- Claim for Feraheme, Injectafer, or Monoferric:
  - Documented diagnosis of iron deficiency anemia **AND**
  - Documented adequate therapeutic trial, intolerance, or contraindication to oral iron therapy (defined as 60 days in the past 90 days) **AND**
  - Documented adequate therapeutic trial, intolerance, or contraindication to at least 2 of the following agents: Infed, Ferrlecit, or Venofer (trial defined as 1 claim in the past 90 days) **AND**
  - Participant is dialysis dependent: Feraheme only
  - For Feraheme or Monoferric: Participant aged 18 years or older

## Denial Criteria

- Therapy will be denied if no approval criteria are met
- Claim for Injectafer or Monoferric: participant is dialysis dependant
- Claim exceeds approved dosing limitations:
  - Feraheme: 34 ml per 25 days
  - Injectafer 100 mg/2 ml vial: 28 ml per 25 days
  - Injectafer 750 mg/15 ml vial: 30 ml per 25 days
  - Injectafer 1,000 mg/20 ml vial: 20 ml per 25 days
  - Monoferric: 10 ml per 25 days

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception code "0681" (Step Therapy)  
Rule Type: CE

## Default Approval Period

6 months

## References

- Injectafer® (ferric carboxymaltose injection) [package insert]. Shirley, NY: American Regent, Inc.; February 2022.
- Feraheme® (ferumoxytol injection) [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.

*SmartPA Clinical Proposal Form*  
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- Monoferric® (ferric derisomaltose) [package insert]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; February 2022.
- KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int Suppl* 2012; 2:279-335. <https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf>
- Short M, et al. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician*. 2013;87(2):98-104. <https://www.aafp.org/afp/2013/0115/p98.html>
- IPD Analytics. Hematologic: Iron Deficiency/Replacement. Accessed May 5, 2023.
- Facts & Comparisons. Iron Parenteral. Accessed May 5, 2023.