



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Iron – Injectable Step Therapy Edit
<b>First Implementation Date:</b>	November 19, 2020
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" 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 4-1-2020 to 3-31-2021			
Drug	Claims	Spend	Avg Spend per Claim
FERAHEME 510 MG/17 ML VIAL	492	\$407,684.72	\$828.62
FERRLECIT 62.5 MG/5 ML VIAL	2,509	\$44,938.70	\$17.91
INFED 100 MG/2 ML VIAL	426	\$45,481.31	\$106.76
INJECTAFER 750 MG/15 ML VIAL	527	\$475,535.26	\$902.34
MONOFERRIC 1,000 MG/10 ML VIAL	0	-	-
TRIFERIC 27.2 MG/5 ML AMP	0	-	-
TRIFERIC 272 MG PWD PKT	0	-	-
VENOFER 100 MG/5 ML VIAL	10,418	\$507,552.28	\$48.71
VENOFER 200 MG/10 ML VIAL	282	\$23,216.07	\$82.32
VENOFER 50 MG/2.5 ML VIAL	7,059	\$131,592.80	\$18.64

**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**:
  - Participant aged 18 years or older **AND**
  - Documented diagnosis of iron deficiency anemia in the past 2 years **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

## 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: 2 vials per 30 days
  - Injectafer: 30 ml per 30 days
  - **Monoferric: 10 ml per 30 days**

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:

<b>X</b>

## 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.; September 2020.
- Feraheme® (ferumoxytol injection) [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; September 2020.
- Monoferric® (ferric derisomaltose) [package insert]. Morristown, NJ: Pharmacosmos Therapeutics Inc.; July 2020.

*SmartPA Clinical Proposal Form*

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- 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: Anemias - Iron Deficiency/Replacement, CAD. Accessed May 4, 2021.
- Facts & Comparisons. Iron Parenteral. Accessed May 4, 2021.

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