

SmartPA Criteria Proposal

Drug/Drug Class:	Iron – Injectable Step Therapy Edit
First Implementation Date:	TBD
Proposed Date:	June 18, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" 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.

Program-Specific Information:

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	Claims	Spend	Avg cost per claim	Cost per package
FERAHEME 510MG/17ML VIAL	540	\$435,175.20	\$805.88	\$1,067.09 per vial MAC
FERRLECIT 62.5MG/5ML VIAL	2,823	\$96,747.23	\$34.27	\$8.00 per vial MAC
INFED 100MG/2ML VIAL	247	\$11,253.38	\$45.56	\$29.08 per vial MAC
INJECTAFER 750MG/15ML VIAL	756	\$665,154.23	\$879.83	\$1,106.40 per vial WAC
TRIFERIC 27.2MG/5ML AMP	0	-	-	\$9.50 per vial WAC
TRIFERIC 272MG PWD PKT	0	-	-	\$80.00 per pkt WAC
VENOFER 100MG/5ML VIAL	9,619	\$459,093.71	\$47.72	\$48.00 per vial WAC
VENOFER 200MG/10ML VIAL	156	\$12,797.62	\$82.03	\$96.00 per vial WAC
VENOFER 50MG/2.5ML VIAL	6,204	\$115,737.18	\$18.65	\$23.80 per vial WAC

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 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 or Injectafer:
 - 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: participant is dialysis dependant
- Claim exceeds approved dosing limitations:
 - Feraheme: 2 vials per 30 days
 - Injectafer: 30ml per 30 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 2020.
- Feraheme® (ferumoxytol injection) [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; February 2018.

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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: Iron Deficiency Anemia / Iron Replacement. Accessed May 5, 2020.
- Facts & comparisons. Iron Parenteral. Accessed May 5, 2020.
- IPD Analytics. New Drug Approval: Accrufer (ferric maltol). August 2019.

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