Clinical Policy Title:	ferumoxytol
Policy Number:	RxA.135
Drug(s) Applied:	Feraheme®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Ferumoxytol (Feraheme®) injection is an iron replacement product. Feraheme® is indicated for the treatment of iron deficiency anemia (IDA) in adult patients

- who have intolerance to oral iron or have had unsatisfactory response to oral iron;
- who have chronic kidney disease (CKD)

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ferumoxytol (Feraheme®)	IDA with or without CKD (adults)	510 mg IV infusion followed by a second 510 mg IV infusion 3 to 8 days later. *For patients receiving hemodialysis, administer after at least one hour of hemodialysis	510 mg per dose -Treatment course: 1020 mg -Treatment may be repeated

Dosage Forms

- Intravenous solution: 510 mg/17 mL (17 mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Iron Deficiency Anemia associated with Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA and CKD;
2. IDA is confirmed by either of the following:
   a. Transferrin saturation (TSAT) ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. If CKD does not require hemodialysis or peritoneal dialysis, oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;

b. Hgb < 7 g/dL;
c. Symptomatic anemia;
d. Severe or ongoing blood loss;
e. Oral iron intolerance;
f. Unable to achieve therapeutic targets with oral iron;
g. Co-existing condition that may be refractory to oral iron therapy;

4. Dose does not exceed 510 mg elemental iron per infusion/injection

Approval Duration
Commercial: 3 months
Medicaid: 3 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA confirmed by any of the following:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hgb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased soluble transferring receptor (sTfR) or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
2. Oral iron therapy is not optimal due to any of the following:
   a. TSAT < 12%;
   b. Hgb < 7 g/dL;
   c. Symptomatic anemia;
   d. Severe or ongoing blood loss;
   e. Oral iron intolerance;
   f. Unable to achieve therapeutic targets with oral iron;
   g. Co-existing condition that may be refractory to oral iron therapy;
3. At the time of the request, member does not have CKD;
4. Dose does not exceed 510 mg elemental iron per infusion/injection.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met all initial approval criteria;
2. Documentation of one of the following laboratory results measured since the last IV iron administration:
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;
3. If request is for a dose increase, new dose does not exceed 510 mg elemental iron per infusion/injection.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met all initial approval criteria;
2. Documentation of one of the following laboratory results measured since the last IV iron administration:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased sTfR or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
3. At the time of the request, member does not have CKD;
4. If request is for a dose increase, new dose does not exceed 510 mg elemental iron per infusion/injection.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hb: hemoglobin
IDA: iron deficiency anemia
TSAT: transferrin saturation
sTfR: soluble transferring receptor

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Examples of OTC Oral Iron Formulations*		
Ferrous fumarate (Ferretts, Ferrimin 150, Hemocyte)	Varies	
Ferrous gluconate (Ferate)		
Ferrous sulfate (BProtected Pedia Iron, Fer-In-Sol, FeroSul, Iron Supplement Childrens, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Myferon 150, NovaFerrum 125, NovaFerrum 50, NovaFerrum Pediatric Drops, Nu-Iron, Poly-Iron 150)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

*Oral formulations include elixirs, liquids, solutions, syrups, capsules, and tablets – including delayed/extended-release tablets.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Contraindication(s): Known hypersensitivity to Feraheme® or any of its components, history of allergic reaction to any intravenous iron product.

- Boxed Warning(s):
  - Serious hypersensitivity/anaphylaxis reaction

APPENDIX D: General Information

- Not applicable

References

1. Feraheme® prescribing information. AMAG Waltham, MA: Pharmaceuticals, Inc.; September 2020. Available from https://www.feraheme.com/. Accessed January 19, 2021.
2. KDIGO 2012 clinical practice guideline for evaluation and management of chronic kidney disease. *Kidney International Supplements.* January 2013; 3(1): 1-136.
3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
5. Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician.* 2013; 87(2): 98-104. http://www.aafp.org/afp/2013/0115/p98.pdf
6. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2018. Available at www.uptodate.com. Accessed January 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. References were updated. 2. Continued Therapy criteria II.A.1 was rephrased to" Currently receiving the medication that has been authorized by RxAdvance…"	05/07/2020	5/21/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Therapeutic alternatives were updated: Deleted the discontinued drugs. 3. Appendix B standard verbiage has been changed	01/14/2021	03/09/2021

and updated.		