Clinical Policy: Ferumoxytol (Feraheme)

Reference Number: PA.CP.PHAR.165
Effective Date: 01/18 Coding Implications
Last Review Date: 07/18 Revision Log

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for the use of ferumoxytol (Feraheme®) injection.

FDA Approved Indication(s)

Feraheme is indicated for the treatment of iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD).

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness that Feraheme is **medically necessary** for members meeting the following criteria:

I. Initial Approval Criteria

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

1. Diagnosis of iron deficiency anemia (IDA) and chronic kidney disease (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.

Approval duration: 3 months

B. Iron Deficiency Anemia not associated with 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.

Approval duration 3 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval Criteria

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

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuation of Care policy (PA.LTSS.PHAR.01) applies;
2. Either of the following measured ≥ 4 weeks after last IV iron administration;
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL.
3. 3. If request is for a dose increase, new dose does not exceed 510 mg elemental iron per infusion/injection.

Approval duration 3 months

B. Iron Deficiency Anemia not associated with Chronic Kidney Disease (must meet all):

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuation of Care policy (PA.LTSS.PHAR.01) applies ;
2. Any of the following measured ≥ 4 weeks after 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.
   a.

Approval duration 3 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuation of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Feraheme (ferumoxytol) is an iron replacement product consisting of a superparamagnetic iron oxide that is coated with a carbohydrate shell which helps to isolate the bioactive iron from plasma components until the iron-carbohydrate complex enters the reticuloendothelial system macrophages of the liver, spleen and bone marrow. The iron is released from the iron-carbohydrate complex within vesicles in the macrophages. Iron then either enters the intracellular storage iron pool (e.g., ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin.

*Formulations:*Intravenous solution:
Feraheme: 510 mg/17 mL (17 mL)

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hb: hemoglobin
IDA: iron deficiency anemia
TSAT: transferrin saturation
sTfR: soluble transferring receptor

References

1. Feraheme prescribing information. AMAG Waltham, MA: Pharmaceuticals, Inc.; March 2015. Available from http://products.sanofi.us/ferrlecit/ferrlecit.html. Accessed October 2017.
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; 2017. Available at www.uptodate.com. Accessed December 2017.
7. Iron only mineral supplement formulas. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at http://www.clinicalpharmacology-ip.com. Accessed December 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

Reviews, Revisions, and Approvals	Date	Approval Date
Dosing added. References reviewed and updated.	02/18	