Clinical Policy: Ferumoxytol (Feraheme)

Reference Number: CP.PHAR.165
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of ferumoxytol (Feraheme®) injection.

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® 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 if receiving an erythropoiesis-stimulating agent (ESA);
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.

Approval duration 3 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval Criteria

A. Iron Deficiency Anemia associated with Chronic Kidney Disease (must meet all):
1. Currently receiving the medication via Centene benefit or member has previously met all initial approval criteria;
2. Either of the following measured ≥ 4 weeks after last IV iron administration;
   a. TSAT ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL if receiving an ESA.

Approval duration 3 months

B. Iron Deficiency Anemia not associated with Chronic Kidney Disease (must meet all):
1. Currently receiving the medication via Centene benefit or member has previously met all initial approval criteria;
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;

Approval duration 3 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy

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)

FDA Approved Indications:
Feraheme is an intravenous iron oxide indicated for:

- Treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD).

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. Ferrlecit prescribing information. Bridgewater, NJ: Sanofi-Aventis, Inc.; April 2015. Available from http://products.sanofi.us/ferrlecit/ferrlecit.html. Accessed February 20, 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. Berns JS. Diagnosis of iron deficiency in chronic kidney disease. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
5. Berns JS. Treatment of iron deficiency in hemodialysis patients. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
6. Berns JS. Treatment of iron deficiency in peritoneal dialysis patients. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
7. Berns JS. Treatment of iron deficiency in nondialysis chronic kidney disease (CKD) patients. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
8. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
9. 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
10. Schrier SL. Causes and diagnosis of iron deficiency and iron deficiency anemia in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
11. Schrier S, Auerbach M. Treatment of iron deficiency anemia in adults. In: UpToDate. Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
12. Mahoney DHM. Iron deficiency in infants and young children: Screening, prevention, clinical manifestations, and diagnosis. In: UpToDate. Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 2017.
13. Mahoney DHM. Iron deficiency in infants and young children: Treatment. In: UpToDate. Waltham, MA: Walters Kluwer Health; 2017. Accessed February 20, 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
Policy developed	01/16	03/16
Labeled and off-labeled use, and diagnostic/follow-up tests, are edited for consistency across ferumoxytol, ferric gluconate, iron sucrose, and ferric carboxymaltose policies, and are made broad enough to capture use in adults, children and pregnancy. The criteria also encompass iron maintenance and replenishment. Diagnostic hemoglobin for anemia in men changed from 13.5 to 13 based on WHO criteria. Age and dose are removed. Hypersensitivity removed as a contraindication.	02/17	03/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.