

Clinical Policy: Ferric Gluconate (Ferrlecit)

Reference Number: PA.CP.PHAR.166

Effective Date: 01/18

Last Review Date: 07/18

[Revision Log](#)
[Coding Implications](#)

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 sodium ferric gluconate complex in sucrose (Ferrlecit[®]) injection.

FDA Approved Indication(s)

Ferrlecit is indicated for the treatment of iron deficiency anemia (IDA) in adult patients and in pediatric patients with chronic kidney disease (CKD) receiving hemodialysis who are receiving supplemental epoetin therapy.

Policy/Criteria

It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Ferrlecit 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) \leq 30%;
 - b. Serum ferritin \leq 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 125 mg of elemental iron per infusion/injection.

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 \leq 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 transferrin 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 Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Either of the following measured ≥ 4 weeks after last IV iron administration:
 - a. TSAT $\leq 30\%$;
 - b. Serum ferritin ≤ 500 ng/mL
3. If request is for a dose increase, new dose does not exceed 125 mg elemental iron per infusion/injection.
 - a.

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 Continuity 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 Hgb < 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.

Approval duration 3 months

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

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

Background

Description/Mechanism of Action:

Ferrlecit (sodium ferric gluconate complex in sucrose injection), an iron replacement product, is used to replete the body content of iron. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport. Additionally, iron is necessary for metabolism and various enzymatic processes.

Formulations:

Intravenous solution:

Ferrlecit: 12.5 mg/mL (5 mL)

Generic: 12.5 mg/mL (5 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 transferrin receptor

References

1. Ferrlecit prescribing information. Bridgewater, NJ: Sanofi-Aventis, Inc.; April 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.

CLINICAL POLICY
Ferric Gluconate



HCPCS Codes	Description
J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg

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