

Clinical Policy: Ferric Gluconate (Ferrlecit)

Reference Number: CP.PHAR.166

Effective Date: 03.01.16

Last Review Date: 02.23

Line of Business: HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Sodium ferric gluconate complex in sucrose (Ferrlecit[®]) injection is an iron replacement product.

FDA Approved Indication(s)

Ferrlecit is indicated for the treatment of iron deficiency anemia (IDA) in adult patients and in pediatric patients age 6 years and older with chronic kidney disease (CKD) receiving hemodialysis who are receiving supplemental epoetin therapy.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation[®] that Ferrlecit is **medically necessary** when the following criteria are met:

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) \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 without Chronic Kidney Disease (off-label) (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);

CLINICAL POLICY
Ferric Gluconate

- 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;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration 3 months**C. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy**A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):**

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Documentation of one of the following laboratory results measured since the last IV iron administration:
 - a. TSAT \leq 30%;

CLINICAL POLICY
Ferric Gluconate

- b. Serum ferritin \leq 500 ng/mL;
3. If request is for a dose increase, new dose does not exceed 125 mg elemental iron per infusion/injection.

Approval duration 3 months**B. Iron Deficiency Anemia without Chronic Kidney Disease (off-label) (must meet all):**

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 \leq 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 is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration 3 months**C. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –

CLINICAL POLICY
Ferric Gluconate

HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of OTC Oral Iron Formulations*		
Ferrous fumarate (Ferretts, Ferrimin 150)	Varies	
Ferrous gluconate (Ferate)		
Ferrous sulfate (BProtected Pedia Iron, Fer-In-Sol, FeroSul, Iron Supplement, Iron Supplement Childrens, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferrix x-150, IFerex 150, NovaFerrum 125, NovaFerrum, 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): Known hypersensitivity to sodium ferric gluconate or any of its inactive components.
- Boxed warning(s): None reported.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IDA with CKD with Hemodialysis: Iron Repletion		
Adults	125 mg by IV infusion or injection per dialysis session. - May require a cumulative dose of 1000 mg over 8 dialysis sessions.	125 mg of elemental iron per dose
Children age ≥ 6 years	1.5 mg/kg administered by IV infusion per dialysis session.	125 mg of elemental iron per dose

CLINICAL POLICY
Ferric Gluconate

VI. Product Availability

Intravenous solution single-dose vial: 12.5 mg/mL (5 mL)

VII. References

1. Ferrlecit prescribing information. Bridgewater, NJ: Sanofi-Aventis, Inc.; December 2020. Available from <http://products.sanofi.us/ferrlecit/ferrlecit.html>. Accessed November 9, 2022.
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. Babitt JL, Eisenga MF, Haase VH, et al. Controversies in optimal anemia management: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Conference. *Kidney Int*. 2021;99(6):1280-1295.
5. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med*. 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
6. 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>
7. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health. Updated periodically. Accessed November 21, 2022.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: - No significant changes - Converted to the new template - Dosing added - References reviewed and updated.	12.01.17	02.18
1Q 2019 annual review; under IDA initial and continuation criteria, a serum ferritin of less than or equal to 500 is edited by deleting the additional requirement of receiving an ESA based on the KDIGO 2012 guidelines which do not include this restriction; under IDA and IDA with CKD continuation criteria, the greater than or equal to 4 week waiting period before retesting after the last IV iron administration is removed per the KDIGO 2012 guidelines which note	11.13.18	02.19

CLINICAL POLICY
Ferric Gluconate

Reviews, Revisions, and Approvals	Date	P&T Approval Date
that only one week need pass before retesting; references reviewed and updated.		
1Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	11.09.19	02.20
1Q 2021 annual review: for iron deficiency anemia without CKD off-label use, added requirement for provider to submit off-label dosing limits per label or practice guidelines; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.18.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.08.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.30.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.20.22	02.23

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

CLINICAL POLICY

Ferric Gluconate

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.

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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.

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