CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Iron Replacement – Ferrlecit Utilization Management Medical Policy
- Ferrlecit® (sodium ferric gluconate complex in sucrose intravenous infusion – sanofi-aventis, generic)

REVIEW DATE: 01/15/2025

OVERVIEW

Ferrlecit, an iron replacement product, is indicated for the treatment of **iron deficiency anemia** in patients ≥ 6 years of age with **chronic kidney disease** (CKD) **receiving hemodialysis** who are receiving supplemental epoetin therapy.[1]

Dosing Information

The recommended dosage of Ferrlecit for the repletion treatment of iron deficiency in hemodialysis patients is 10 mL of Ferrlecit (125 mg of elemental iron).[1] For repletion treatment most adult patients may require a cumulative dose of 1000 mg of elemental iron administered over 8 dialysis sessions. The recommended pediatric dosage in hemodialysis patients is 0.12 mL/kg Ferrlecit (1.5 mg/kg of elemental iron) administered by intravenous (IV) infusion per dialysis session. The maximum pediatric dosage should not exceed 125 mg per dose.

Guidelines

The Kidney Disease: Improving Global Outcomes clinical practice guideline for anemia in CKD (2025) make various recommendations regarding iron therapy.[2] For patients with CKD and anemia receiving hemodialysis, initiation of IV iron is suggested if transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For patients with CKD and anemia who are not receiving hemodialysis or treated with peritoneal dialysis, initiation of oral or IV iron is suggested if TSAT is < 40% and ferritin < 100 ng/mL or if TSAT < 25% with ferritin ≥ 100 ng/mL and < 300 ng/ml. For patients with CKD and profound iron deficiency (TSAT < 20% and ferritin < 30 ng/mL) but no anemia, consider treatment with oral or IV iron. Additional practice points are noted such as a switch from oral to IV iron if there is an insufficient effect of an optimal oral regimen after 1 to 3 months. KDIGO also notes the choice between different formulations of IV iron should be guided by individual considerations and recommended dosing schedules.

The National Comprehensive Cancer Network guidelines on hematopoietic growth factors (version 1.2025 – October 11, 2024) discuss the management of cancer- and chemotherapy-induced anemia.[3] Treatment for iron deficiency is guided by iron status which is defined in the guidelines as: absolute iron deficiency, functional iron deficiency, possible functional iron deficiency, or no iron deficiency and use in combination with erythropoiesis-stimulating agents. IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%) in patients who are also receiving an ESA, functional iron deficiency (ferritin = 30 to 500 ng/mL and TSAT < 50%), and for select patients with possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%). All recommendations are category 2A for each product.

The American College of Cardiology/American Heart Association guideline for the management of heart failure (2022) states that in patients with heart failure with reduced ejection fraction (left ventricular ejection fraction ≤ 40%), absolute iron deficiency (ferritin < 100 ng/mL) or functional iron deficiency (ferritin = 100 to 300 mg/mL if TSAT is < 20%), and with or without anemia, IV iron replacement is reasonable to improve functional status and quality of life (2a recommendation).[4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Ferrlecit. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ferrlecit as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Ferrlecit to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ferrlecit is recommended in those who meet one of the following criteria:

FDA-Approved Indication

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1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis**. Approve for 3 years.

Other Uses with Supportive Evidence

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2. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 6 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a nephrologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

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3. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 6 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has tried oral iron supplementation; AND
       - **b)** According to the prescriber, oral iron supplementation was ineffective or intolerable; OR
     - **ii.** According to the prescriber, patient has a condition that will interfere with oral iron absorption; OR

       Note: Examples of conditions that may interfere with oral iron absorption may include inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
     - **iii.** Patient is currently receiving an erythropoiesis-stimulating agent; OR

       Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product.
     - **iv.** The medication is being requested for cancer- or chemotherapy-related anemia.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

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4. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 6 years of age; AND
   B) The medication is being prescribed by or in consultation with a cardiologist or hematologist.

   Dosing. Approve up to a maximum cumulative total dose of 1000 mg given intravenously per 30 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ferrlecit is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ferrlecit® [prescribing information]. Bridgewater, NJ: sanofi-aventis; March 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. 2025 KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease (*November 2024 Public Review Draft*). Available at: https://kdigo.org/guidelines/anemia-in-ckd/. Accessed on January 8, 2025
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 7, 2025.
4. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in *J Am Coll Cardiol*. 2023 Apr 18;81(15):1551]. *J Am Coll Cardiol*. 2022;79(17):e263-e421.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/10/2024
Annual Revision	**Iron Deficiency Anemia, Other:** The verbiage "patient has a condition which, per the prescriber, will interfere with oral iron absorption" was updated to "according to the prescriber, patient has a condition that will interfere with oral iron absorption". Examples of "conditions that may interfere with oral iron absorption" were moved from the criteria to a Note. The term "erythroid-stimulating agents" was updated to "erythropoiesis-stimulating agents".	01/15/2025