Policy:	**Iron Replacement – Sodium Ferric Gluconate Utilization Management Medical Policy** • Ferrlecit® (sodium ferric gluconate complex in sucrose intravenous infusion – sanofi-aventis, generic)
DATE:	02/04/2026
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	All States
Applicable NCDs, LCDs, and/or LCAs	NCD 110.10

SUMMARY OF EVIDENCE

Sodium ferric gluconate complex in sucrose (Ferrlecit, generic), an intravenous iron replacement product, is indicated for the treatment of **iron deficiency anemia** in adult and pediatric patients ≥ 6 years of age with **chronic kidney disease** (CKD) **receiving hemodialysis** who are receiving supplemental epoetin therapy.[1]

Dosing Information

The dosage of sodium ferric gluconate is expressed in terms of mg of elemental iron, with each 5 mL containing 62.5 mg of elemental iron. The recommended dosage of sodium ferric gluconate for the repletion treatment of iron deficiency in hemodialysis patients is 10 mL (125 mg of elemental iron) administered by intravenous (IV) infusion per dialysis session. 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 (1.5 mg/kg of elemental iron) administered by IV infusion per dialysis session. The maximum pediatric dosage should not exceed 125 mg per dose. Treatment may be repeated if iron deficiency reoccurs.

Guidelines

Anemia in CKD

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.

Cancer-Related Anemia

The National Comprehensive Cancer Network guidelines on hematopoietic growth factors (version 3.2026 – December 5, 2025) 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 (ESAs). IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%) and possible functional iron deficiency (ferritin > 500-800 ng/mL and TSAT < 50%) in selected patients (with the goal of avoiding allogeneic transfusion). IV iron therapy is also considered an option in combination with ESAs for the treatment of

functional iron deficiency (ferritin 30 to 500 ng/mL and TSAT < 50%) in patients receiving myelosuppressive chemotherapy without curative intent and absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%) in patients who do not experience an increase in hemoglobin after four weeks of IV or oral iron supplementation. All recommendations are category 2A for each product.

Heart Failure

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]

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of sodium ferric gluconate. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does <u>not</u> necessarily mean that the applicable condition or diagnosis is excluded from coverage.

<u>Note</u>: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or

supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a [@] below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a [#] below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis. ^

Criteria. Approve for 3 years.

2. Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis. ^

Criteria. Approve for 1 year if the patient is ≥ 6 years of age. [IC-L]

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

Other Uses with Supportive Evidence

3. Iron Deficiency Anemia, Other. [@]

Criteria. Approve for 1 year if the patient meets the following (A and B):
A) The patient is ≥ 6 years of age; AND
B) The patient meets one of the following (i, ii, iii, or iv):
- **i.** The patient meets both of the following (a and b):
  - **a)** The 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. @

Criteria. Approve for 1 year if the patient is ≥ 6 years of age.

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.

SOURCES OF INFORMATION

1. Ferrlecit® [prescribing information]. Bridgewater, NJ: sanofi-aventis; October 2025.
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 December 15, 2025.
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 3.2026 – December 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 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.
5. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for **Intravenous Iron Therapy** (110.10). [Version Number 1, Effective date: 10/1/2001. Revision date: 01/2021. Accessed February 4, 2026].

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Policy	02/05/2020
Selected Revision	**Iron Deficiency Anemia in Chronic Kidney Disease** was separated into two conditions, **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis** and **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis.** The indication for **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis** will not be targeted in this policy and all requests are to approve for 3 years.	03/04/2020
Select revision	Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles."	04/03/2020
Policy review	No criteria changes.	12/30/2020

Policy review	No criteria changes.	12/15/2021
Policy review	No criteria changes.	12/14/2022
Policy review	No criteria changes.	02/21/2024
Policy 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".	01/28/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/10/2025
Policy revision	The name of the policy was changed from *Iron Replacement – Ferrlecit* to as listed. Throughout the policy, reference to "Ferrlecit" was changed to "sodium ferric gluconate".	02/04/2026