Drug Coverage Policy

Effective Date.....4/1/2026
Coverage Policy Number.....IP0749
Policy Title.....Monoferric

Iron Replacement – Monoferric

- Monoferric® (ferric derisomaltose intravenous infusion – Pharmacosmos)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Monoferric, an intravenous iron replacement product, is indicated for the treatment of **iron deficiency anemia** in patients ≥ 18 years of age for the following uses:[1]

- Intolerance to oral iron or have had unsatisfactory response to oral iron.
- Non-hemodialysis dependent **chronic kidney disease** (CKD).

Dosing Information
The recommended dose of Monoferric is 1000 mg in patients weighing ≥ 50 kg administered by intravenous (IV) infusion as a single dose per treatment cycle.[1] For patients weighing < 50 kg, the recommended dose is 20 mg/kg actual body weight administered as a single dose per treatment cycle. Treatment may be repeated if iron deficiency anemia 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]

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Monoferric. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Monoferric as well as the monitoring required for adverse events and long-term efficacy, particular approvals require Monoferric to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Monoferric is considered medically necessary when ONE of the following are met:

FDA-Approved Indications

1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis**. Approve for 1 year if the patient meets **ALL** of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with a nephrologist or hematologist.
   C) Preferred product criteria is met for the product(s) as listed in the below table(s)

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

2. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets **ALL** of the following (A and B):
   A) Patient is ≥ 18 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 dose of 1000 mg given intravenously per 30 days.

Other Uses with Supportive Evidence

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

4. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the patient meets **ALL** of the following (A and B):
   A) Patient is ≥ 18 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 dose of 1000 mg given intravenously per 30 days.

Employer Plans:

Product	Criteria
Monoferric (ferric derisomaltose)	**Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on dialysis.** Patient meets **ONE** of the following (1 or 2): 1. Patient has tried at least one of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR

Product	Criteria
	2. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.

Individual and Family Plans:

Product	Criteria
Monoferric (ferric derisomaltose)	**Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are <u>not</u> on dialysis.** Patient meets **ONE** of the following (1 <u>or</u> 2): 1. Patient has tried at least <u>one</u> of the following: INFeD, sodium ferric gluconate complex (Ferrlecit, generics), Venofer; OR 2. Patient has initiated therapy with the requested medication and requires further medication to complete the current course of therapy.

Conditions Not Covered

Monoferric for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note:
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1437	Injection, ferric derisomaltose, 10 mg

References

1. Monoferric® intravenous infusion [prescribing information]. Holbaek, Denmark: Pharmacosmos; November 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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	09/15/2025
Annual Revision	Updated Preferred Product Criteria for the disease-state, Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis: a trial of both sodium ferric gluconate complex (Ferrlecit, generics) and Venofer is required (previously one product required); INFeD removed from the list of preferred products; continuation-of-therapy criterion removed.	4/1/2026

The policy effective date is in force until updated or retired.