UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Iron Replacement – Monoferric Utilization Management Medical Policy
- Monoferric® (ferric derisomaltose intravenous infusion – Pharmacosmos)

REVIEW DATE: 01/10/2024

OVERVIEW

Monoferric, an 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 **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 administered as a single dose per treatment cycle.

Guidelines

The Kidney Disease: Improving Global Outcomes guidelines for anemia in CKD (2012) make various recommendations regarding iron therapy.[2] For adults with CKD and anemia not on iron or erythroid stimulating agent (ESA) therapy, a trial of IV iron (or in non-dialysis patients with CKD, alternatively, a 1 to 3 month trial of oral iron therapy) is recommended if an increase in hemoglobin (Hb) concentration without starting ESA treatment is desired, and transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For adults with CKD on ESA therapy who are not receiving iron supplementation, a trial of IV iron (or in non-dialysis CKD patients, alternatively, a 1 to 3 month trial of oral iron therapy) is recommended if an increase in Hb concentration or a decrease in ESA dose is desired, and TSAT is ≤ 30% and ferritin is ≤ 500 ng/mL. For all pediatric patients with CKD with anemia not on iron or ESA therapy, oral iron (or IV iron in patients receiving hemodialysis) is recommended when TSAT is ≤ 20% and ferritin is ≤ 100 ng/mL. For all pediatric patients with CKD who are receiving ESA therapy but not receiving iron supplementation, it is recommended to administer oral iron (or IV iron for patients receiving hemodialysis) to maintain TSAT > 20% and ferritin > 100 ng/dL.

The National Comprehensive Cancer Network guidelines on Hematopoietic Growth Factors (version 2.2024 – December 12, 2023) 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. IV iron therapy is considered an option for patients with absolute iron deficiency (ferritin < 30 ng/mL and TSAT < 20%), functional iron deficiency (ferritin = 30 to 500 ng/mL and TSAT < 50%) in patients who are also receiving an ESA, and for select patients with possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%).

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]

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POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Monoferric. 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 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis**. Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Monoferric is prescribed by or in consultation with a nephrologist or hematologist.

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

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2. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets 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.** Patient has a condition which, per the prescriber, will interfere with oral iron absorption (e.g., inflammatory bowel disease, Crohn's disease); OR
     - **iii.** Patient is currently receiving an erythroid stimulating agent; OR
       Note: Examples of erythroid 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

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

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4. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the patient meets the following (A and B):

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A) Patient is ≥ 18 years of age; AND
B) Monoferric 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Monoferric 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. Monoferric® intravenous infusion [prescribing information]. Holbaek, Denmark: Pharmacosmos; August 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012;2(Suppl):279-335.
3. The NCCN Hematopoietic Growth Factors Guidelines in Oncology (version 2.2024 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 4, 2024.
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.	12/14/2022
Annual Revision	No criteria changes.	01/10/2024

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