Monoferric® (ferric derisomaltose)

When requesting Monoferric® (ferric derisomaltose), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Monoferric is indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron
- who have non-hemodialysis dependent chronic kidney disease

Approved Off-Label Compendial Uses

- Iron deficiency anemia in patients with chronic kidney disease who are on dialysis
- Iron deficiency in patients with heart failure

Coverage Guidelines

Iron Deficiency Anemia in Patients with Chronic Kidney Disease

The individual must meet both of the following criteria for approval:
- Is 18 years of age or older;
- Monoferric is prescribed by or in consultation with a nephrologist or hematologist.

Iron Deficiency Anemia, Other

The individual must meet both of the following criteria for approval:
- Is 18 years of age or older;
- Must meet one of the following:
    - Has tried oral iron supplementation but was ineffective or intolerable; OR
    - Has a condition which will interfere with oral iron absorption (e.g., inflammatory bowel disease); OR
    - Is currently receiving an erythropoiesis-stimulating agent (e.g., an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product); OR
    - Monoferric is being requested for cancer or chemotherapy-related anemia.

Iron Deficiency in Patients with Heart Failure

The individual must meet both of the following criteria for approval:

- Is 18 years of age or older;
- Monoferric is prescribed by or in consultation with a cardiologist or hematologist.

Approval duration: 12 months

Dosing Recommendations

For patients weighing 50 kg or more:
The recommended dose is 1,000 mg administered by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs.

For patients weighing less than 50 kg:
The recommended dose is 20 mg/kg actual body weight administered by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs.

References

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