PRIOR AUTHORIZATION POLICY

POLICY: Iron Replacement – INFeD Prior Authorization Policy
- INFeD® (iron dextran intravenous or intramuscular injection – Allergan)

REVIEW DATE: 01/10/2024

OVERVIEW

INFeD, an iron replacement product, is indicated for the treatment of documented **iron deficiency** in patients ≥ 4 months of age who have intolerance to oral iron or have had an unsatisfactory response to oral iron.[1]

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 intravenous (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]

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Iron Deficiency Anemia, Other.** Approve for 1 year if the patient meets ONE of the following (A, B, C, or D):
   - **A)** Patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried oral iron supplementation; AND
     - **ii.** According to the prescriber, oral iron supplementation was ineffective or intolerable; OR
   - **B)** Patient has a condition which, per the prescriber, will interfere with oral iron absorption (e.g., inflammatory bowel disease, Crohn's disease); OR
   - **C)** 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.
   - **D)** The medication is being requested for cancer- or chemotherapy-related anemia.

Other Uses with Supportive Evidence

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

3. **Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are not on Dialysis**. Approve for 1 year if the medication is prescribed by or in consultation with a nephrologist or hematologist.

4. **Iron Deficiency Associated with Heart Failure.** Approve for 1 year if the medication is being prescribed by or in consultation with a cardiologist or hematologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of INFeD 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. INFeD® [prescribing information]. Madison, NJ: Allergan; September 2021.
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.