PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/14/2022

OVERVIEW

INFeD, an iron replacement product, is indicated for the treatment of patients ≥ 4 months of age with documented **iron deficiency 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 1.2023 – December 2, 2022) discuss the management of cancer- and chemotherapy-induced anemia.[3] 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%), and possible functional iron deficiency (ferritin = 501 to 800 ng/mL and TSAT < 50%).

A 2017 focused update of the 2013 American College of Cardiology Foundation/American Heart Association guideline for the management of heart failure states that in patients with New York Heart Association class II or III heart failure, absolute iron deficiency (ferritin < 100 ng/mL) or functional iron deficiency (ferritin = 100 to 300 mg/mL if transferring saturation is < 20%), and with or without anemia, IV iron replacement may be reasonable to improve function status and quality of life.[4] Benefits noted with IV iron therapies included improvements in the six-minute walk test and improved functional capacity.

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.

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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]. Parsippany, NJ: Actavis; April 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 1.2023 – December 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/clinical.asp. Accessed on December 9, 2022.
4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. *J Am Coll Cardiol*. 2017;70(6):776-803.

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