



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 18, 2025

## **Accrufer® (ferric maltol)**

**LENGTH OF AUTHORIZATION:** Initial - 3 months  
Continuation - 12 months

### **REVIEW CRITERIA:**

- Patient must be  $\geq 18$  years of age; **AND**
- Patient must have a diagnosis of iron deficiency anemia associated with one of the following diagnoses:
  - **Inflammatory bowel disease** (e.g., Crohn's disease, ulcerative colitis) with baseline hemoglobin 9.5 g/dL to 12 g/dL for women or 9.5 g/dL to 13 g/dL for men and serum ferritin  $< 30$  mcg/L. (*Official labs drawn within 30 days of the PA submission confirming the following must be provided*).
- **-OR-**
  - **Non-dialysis dependent chronic kidney disease** (CKD) with baseline hemoglobin 8 g/dL to 11 g/dL, serum ferritin  $< 250$  mcg/L with a transferrin saturation (TSAT)  $< 25\%$  **or** serum ferritin  $< 500$  mcg/L with a TSAT  $< 15\%$ . (*Official labs drawn within 30 days of the PA submission confirming the following must be provided*).
- Patient has documented trial and failure on at least two of the following oral iron therapies due to lack of efficacy or inability to tolerate oral iron replacement products.
  - Ferrous sulfate
  - Ferrous gluconate
  - Ferrous fumarate
  - Iron polysaccharide complex
- Patient will not receive IV iron supplementation while taking Accrufer.

### **CONTINUATION OF THERAPY:**

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response compared to baseline labs (supporting documentation and official lab results required); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

### **DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 30 mg capsules