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 ≥ 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