Clinical Policy: Ferric Maltol (Accrufer)

Reference Number: PA.CP.PMN.213
Effective Date: 11/2022
Last Review Date: 10/2024

Description
Ferric maltol (Accrufer™) is an iron replacement product.

FDA Approved Indication(s)
Accrufer is indicated for the treatment of iron deficiency in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Accrufer is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Iron Deficiency (must meet all)**:**

1. Diagnosis of iron deficiency;
2. Age ≥ 18 years;
3. Failure of two oral iron products (*must be different salts*), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 60 mg (2 capsules) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Iron Deficiency (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 mg (2 capsules) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ferrous fumarate (Ferrimin 150, Ferretts)	PO; dose and frequency varies	Varies
ferrous gluconate (Ferate)	PO; dose and frequency varies	Varies
ferrous sulfate (Fer-In-Sol, FeroSul, Iron Supplement, Slow Fe, Slow Iron)	PO; dose and frequency varies	Varies
polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferric-X 150, iFerex 150, NovaFerrum, Nu-iron 150, Poly-Iron 150)	PO; dose and frequency varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to the active substance or any excipient; hemochromatosis and other iron overload syndromes; patients receiving repeated blood transfusions
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Iron deficiency	30 mg PO BID, taken 1 hour before or 2 hours after a meal Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks of treatment is required. The treatment should be	60 mg/day

Indication	Dosing Regimen	Maximum Dose
	continued as long as necessary until ferritin levels are within the normal range	

VI. Product Availability

Capsule: 30 mg

VII. References

1. Accrufer Prescribing Information. London: Shield Therapeutics; October 2023. Available at: https://www.accruferhcp.com/PrescribingInformation. Accessed July 19, 2024.
2. Camaschella C. Iron-Deficiency Anemia. N Engl J Med. 2015; 372: 1832-43.
3. DeLoughery TG, Jackson CS, Ko CW, Rockey DC. AGA clinical practice update on management of iron deficiency anemia: expert review. Clin Gastroenterol Hepatol. 2024;22(8):1575-1583.
4. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health. Updated periodically. Accessed August 7, 2024.

Reviews, Revisions, and Approvals	Date
Policy created	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023
4Q 2024 annual review: no significant changes; references reviewed and updated.	10/2024