Clinical Policy: Ferric Maltol (Accrufer)

Reference Number: ERX.NPA.127
Effective Date: 12.01.19
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or member has previously met initial approval criteria;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ferrous fumarate (Ferrimin 150, Ferretts, Ferrocite, Hemocyte)	PO; dose and frequency varies	Varies
ferrous gluconate (Fergon, Ferrotabs)	PO; dose and frequency varies	Varies
ferrous sulfate (Feosol, Ferro-Bob, FerrouSul)	PO; dose and frequency varies	Varies
polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferric-X 150, iFerex 150, Myferon 150, NovaFerrum 50, Nu-iron 150, PIC 200, 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 continued as long as necessary until ferritin levels are within the normal range	60 mg/day

VI. Product Availability

Capsule: 30 mg

VII. References

1. Accrufer Prescribing Information. London: Shield Therapeutics; October 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212320Orig1s000lbl.pdf. Accessed August 1, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.03.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.04.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.01.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.