Clinical Policy: Ferric Maltol (Accrufer)

Reference Number: CP.PMN.213
Effective Date: 09.03.19
Last Review Date: 11.20
Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation® 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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 Centene benefit and documentation supports positive response to therapy.
   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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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; July 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212320Orig1s000lbl.pdf. Accessed August 4, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.03.19	11.19
4Q 2020 annual review: no significant changes; removed references to HIM non-formulary policy and finalized HIM line of business; references reviewed and updated.	08.04.20	11.20

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.