Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

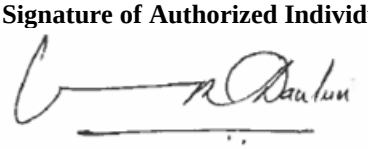
Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PMN.213	**Effective Date: 11/2022** **Revision Date: 10/2022**
Policy Name: Ferric Maltol (Accrufer)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Ferric Maltol (Accrufer)

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

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 both of the following (a and b):
   a. 60 mg per day;
   b. 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.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 60 mg per day;
   b. 2 capsules per day.

4. 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.LTSS.PHAR.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 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	60 mg/day

Indication	Dosing Regimen	Maximum Dose
	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	

VI. Product Availability

Capsule: 30 mg

VII. References

1. Accrufer Prescribing Information. London: Shield Therapeutics; March 2022. Available at: https://www.accruferhcp.com/sites/default/files/pdf/Accrufer_PI_Mar_2022.pdf. Accessed August 2, 2022.
2. Camaschella C. Iron-Deficiency Anemia. N Engl J Med. 2015; 372: 1832-43.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2022	