Clinical Policy Title:	Ferric maltol
Policy Number:	RxA.21
Drug(s) Applied:	Accrufer™
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Ferric maltol (Accrufer™) is an iron replacement product. It is indicated for the treatment of iron deficiency in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Ferric maltol (Accrufer™)	Iron deficiency	30 mg PO Twice Daily, 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

Dosage Forms

- Capsule: 30 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Iron Deficiency (must meet all):

1. Documented diagnosis of iron deficiency;
2. Age 18 years of age or older;
3. Failure of two oral iron products (*must be different salts*) of four weeks in duration for each, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 60 mg (2 capsules) per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Iron Deficiency (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ferrous fumarate (Ferrimin® 150, Ferretts®, Ferrocite®, Hemocyte®)	PO; dose and frequency varies	Varies
ferrous gluconate (Fergon®)	PO; dose and frequency varies	Varies
ferrous sulfate (Feosol®)	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, 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.

APPENDIX D: General Information

- Ferric maltol delivers iron for uptake across the intestinal wall and transfer to transferrin and ferritin.

Replaces iron, found in hemoglobin, myoglobin, and other enzymes; allows the transportation of oxygen via hemoglobin.

- The most common adverse reactions (incidence > 1%) are flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension.

References

1. Accrufer Prescribing Information. London: Shield Therapeutics; July 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212320Orig1s000lbl.pdf. Accessed January 29, 2021.
2. Ferric maltol. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; n.d. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed January 29, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1) Clinical policy title was updated as "Ferric maltol". 2) Line of business policies applies to All lines of business. 3) Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy." 4) Appendix D was updated. 5) References were reviewed and updated.	01/29/2021	03/09/2021