MEDICAL MUTUAL®

Drug Policy

Policy:	Accrufer (ferric maltol)	Annual Review Date: New Policy Last Revised Date: 06/17/2021

OVERVIEW

Accrufer is ferric maltol, a stable, non-salt form of oral iron replacement for the treatment of iron deficiency in adults. The FDA labeling includes similar potential side effects as other oral iron products, but studies showed that gastrointestinal events occurred less frequently. An added benefit of Accrufer is its insignificant risk of anaphylaxis, unlike intravenously administered iron.

POLICY STATEMENT

This policy involves the use of Accrufer. Prior authorization is recommended for pharmacy benefit coverage of Accrufer. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Accrufer as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Accrufer be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Accrufer is recommended in those who meet the following criteria:

1. **Iron Deficiency Anemia without Chronic Kidney Disease**
   Criteria. *Patient must meet the following criteria.*

   A. Patient is 18 years of age or older; AND

   B. Patient has an intolerance to or has had an unsatisfactory response to previous OTC iron therapy

   C. Iron deficiency lab values that meet the following (i or ii, and iii):

   i. Hb of 9.5-12g/dL for women; OR
   ii. Hb of 9.5-13g/dL for men; AND

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iii. Ferritin < 30ug/L

Initial Approval/ Extended Approval.
A) *Initial Approval:1 year*
B) *Extended Approval:1 year*

2. Iron Deficiency Anemia and Non-Dialysis Dependent CKD
Criteria. *Patient must meet the following criteria*

A. Patient is 18 years of age or older; AND

B. Patient has an intolerance to or has had an unsatisfactory response to previous OTC iron therapy

C. Iron deficiency lab values that meet the following (i, ii and iii):

i. Hb of 8-11g/dL for women; AND
ii. Ferritin < 25 ug/L; AND
iii. TSAT < 25%

Initial Approval/ Extended Approval.
A) *Initial Approval:1 year*
B) *Extended Approval:1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Accrufer has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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REFERENCES

1. Accrufer [prescribing information]. Gateshead Quays, UK: Shield Therapeutics; July 2019

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