Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
# Accrufer (ferric maltol)

*Effective: October 14, 2025*

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| **Guideline Type** | ☒ Prior Authorization<br>☒ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

**Accrufer (ferric maltol)** is an iron replacement product indicated for the treatment of iron deficiency in adults.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Accrufer (ferric maltol) for patients when all of the following criteria are met:

1. Documented diagnosis of iron deficiency

**AND**

2. Patient is 18 years of age or older

**AND**

3. Patient has had an inadequate response or intolerance to at least two oral iron therapies (ferrous sulfate, ferrous gluconate, ferrous fumarate)

## Limitations

- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

## Codes

None

## References

1. Accrufer (ferric maltol) [prescribing information]. Wellesley Hills, MA: Shield Therapeutics Inc; December 2023.

## Approval And Revision History

October 8, 2024: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guideline effective January 1, 2025.

Subsequent endorsement date(s) and changes made:

- October 14, 2025: No changes.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are

developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.