Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Topical Antifungal Agents

Effective: August 11, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

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

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

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

Topical antifungal agents policy is applicable for **Ertaczo (sertaconazole) and Luliconazole (generic Luzu).**

Ertaczo (sertaconazole) is an azole antifungal indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older, cause by: *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.

Luliconazole (generic Luzu) is an azole antifungal indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Ertaczo (sertaconazole) and generic luliconazole for patients when **ALL** of the following criteria are met:

Initial therapy:

1. The patient has had a trial and failure, inadequate response, or contraindication to two formulary alternatives (e.g., ketoconazole 2% cream, ciclopirox 0.77%, econazole 1% cream)

Reauthorization:

1. Documentation that patient has shown improvement on the requested medication

Limitations

- Approval for Ertaczo and generic luliconazole will be limited to 12 months.
- 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.

Codes

None

References

1. Ertaczo (sertaconazle nitrate) [prescribing information]. Biloxi, MS. Lacer Pharma, LLC. December 2024.
2. Luzu (luliconazole) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- August 13, 2024: No changes

- August 12, 2025: Removed Mentax from the Medical Necessity Guideline due to product discontinuation. Effective 9/1/25.
- August 11, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

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.