MEDICAL MUTUAL®

Drug Policy

Policy:	Luzu (luliconazole)	Annual Review Date: 09/21/2023 Last Revised Date: 09/21/2023

OVERVIEW

Luzu is an azole antifungal indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by Trichophyton rubrum and Epidermophyton floccosum. Luzu can be used in adults and children 12 years of age and older for the treatment of tinea pedis and tinea cruris or in adults and children 2 years of age and older for the treatment of tinea corporis.

POLICY STATEMENT

This policy involves the use of Luzu and generic luliconazole. Prior authorization is recommended for pharmacy benefit coverage of Luzu and generic luliconazole. 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.

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 Luzu is recommended in those who meet the following criteria:

1. **Tinea Corporis, Tinea Cruris, interdigital Tinea Pedis**
   Criteria. *Patient must meet the following criteria*

   Approve if the patient meets the following (a, b, AND c):

   a. The patient has a diagnosis of tinea corporis, tinea cruris, or interdigital tinea pedis (present between the toes); AND
   b. The patient is 12 years of age or older for diagnoses of tinea pedis and tinea cruris OR 2 years of age or older for diagnosis of tinea corporis; AND
   c. The patient has had an inadequate response to a trial of FOUR topical antifungal agents

Initial Approval/ Extended Approval
A) *Initial Approval:* 1 month (30 days)
B) *Extended Approval:* not recommended

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Luzu and generic luliconazole have 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.

REFERENCES

1. Luliconazole. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated November 06, 2019 . Accessed on 11 August 2020.
2. Luzu topical cream [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. April 2020.