Pharmacy Medical Necessity Guidelines:
Antifungal Medications, Topical

Effective: June 1, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td>RX</td>
<td>√</td>
</tr>
</tbody>
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Pharmacy (RX) or Medical (MED) Benefit

Department to Review: RXUM

Fax Numbers:
RXUM: 617.673.0988

This Pharmacy Medical Necessity Guidelines applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

OVERVIEW

**FDA-APPROVED INDICATIONS**

Topical antifungal agents are indicated for the treatment of tinea corporis (ringworm), tinea cruris (jock itch), and tinea pedis (athlete’s foot) caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*; tinea (pityriasis) versicolor caused by *Pityrosporum orbiculare* (also known as *Malassezia furfur*); cutaneous candidiasis caused by *Candida* sp.; and seborrheic dermatitis

### Topical Antifungal Medications*

<table>
<thead>
<tr>
<th>Preferred Products</th>
<th>Non-Preferred Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclopirox 0.77% Cream, Gel</td>
<td>Ciclopirox 0.77% Suspension, Shampoo</td>
</tr>
<tr>
<td>Ciclopirox 8% Solution</td>
<td>Naftifine 2% Cream; 1% Gel (Naftin)</td>
</tr>
<tr>
<td>Clotrimazole Cream, Lotion, Solution</td>
<td>Oxiconazole Cream (Oxistat)</td>
</tr>
<tr>
<td>Clotrimazole/Betamethasone Cream, Lotion</td>
<td>Econazole Foam (Ecoza)</td>
</tr>
<tr>
<td>Econazole Cream</td>
<td>Efinaconazole Soln (Jublia)</td>
</tr>
<tr>
<td>Ketoconazole Cream, Shampoo</td>
<td>Luliconazole Cream (Luzu)</td>
</tr>
<tr>
<td>Miconazole Cream, Powder (OTC)</td>
<td>Sulconazole Cream, Soln (Exelderm)</td>
</tr>
<tr>
<td>Nystatin Cream, Ointment, Powder</td>
<td>Nystatin/Triamcinolone Cream, Ointment</td>
</tr>
<tr>
<td>Terbinafine Cream (OTC)</td>
<td></td>
</tr>
</tbody>
</table>

*May not be inclusive of all topical antifungal medications
**COVERAGE GUIDELINES**

The plan may authorize coverage of a topical antifungal medication for Members when criteria for a particular regimen are met and limitations do not apply:

1. The Member had an insufficient response to therapy with at least two preferred antifungal agents, or with individual agents if the request is for a combination product

**If the request is for treatment of onychomycosis of the nail,**

1. The provider documented the need to avoid systemic antifungal therapies

   **AND**

2. The Member had an insufficient response to a full course of therapy with ciclopirox 8% topical solution

**Upon renewal,**

1. The Member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is medically necessary.

**LIMITATIONS**

1. Approval will be limited to one year.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

**CODES**

None

**REFERENCES**


**APPROVAL HISTORY**

December 9, 2014: Reviewed by Pharmacy & Therapeutics Committee. Incorporated Jublia, Kerydin Luzu; modified approval to one year with change in renewal criteria; modified criteria for onychomycosis with preferred therapy with ciclopirox; updated table with preferred therapies.

Subsequent endorsement date(s) and changes made:

- November 10, 2015: Kerydin removed since it is a non-covered medication; most strengths removed from reference table; no changes in clinical content.
- January 1, 2016: Administrative change to rebranded template.
- February 14, 2017: Clarified that ciclopirox solution and ciclopirox gel do not require prior authorization.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Added language regarding the review of brand name products with AB-rated generics to the limitations section.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s
benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink® Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.