Pharmacy Medical Necessity Guidelines: Antifungal Medications, Topical

Effective: July 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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*	
Preferred Products	**Ciclopirox 0.77% Cream, Gel**
	Ciclopirox 8% Solution
	Clotrimazole Cream, Lotion, Solution
	Clotrimazole/Betamethasone Cream, Lotion
	Econazole Cream
	Ketoconazole Cream, Shampoo
	Miconazole Cream, Powder (OTC)
	Nystatin Cream, Ointment, Powder
	Nystatin/Triamcinolone Cream, Ointment
	Tolnaftate cream, powder, aerosol, solution (OTC)
Non-Preferred Products	Ciclopirox 0.77% Suspension, Shampoo
	Naftifine 2% Cream; 1% Gel (Naftin)
	Oxiconazole Cream, Lotion (Oxistat)
	Econazole Foam (Ecoza)
	Efinaconazole Solution (Jublia)
	Luliconazole Cream (Luzu)
	Sulconazole Cream, Solution (Exelderm)

*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

1. Ecoza (econazole) [prescribing information]. Mahwah, NJ: Glenmark Therapeutics, Inc; November 2019.
2. Ertaczo [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; November 2017.
3. Exelderm (sulconazole nitrate cream) [prescribing information]. Cranbury NJ: Sun Pharmaceutical Industries, Inc; May 2018.
4. Jublia (efinaconazole) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; April 20206.
5. Luzu (luliconazole) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.
6. Naftin (naftiline) [prescribing information]. Roswell, GA: Sebele Pharmaceuticals Inc; April 2018.
7. Oxistat (oxiconazole) [prescribing information]. Melville, NY: Fougera Pharmaceuticals; January 2012.

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:

1. November 10, 2015: Kerydin removed since it is a non-covered medication; most strengths removed from reference table; no changes in clinical content.
2. January 1, 2016: Administrative change to rebranded template.
3. February 14, 2017: Clarified that ciclopirox solution and ciclopirox gel do not require prior authorization.
4. May 9, 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.
5. December 11, 2018: Effective 1/1/2019, removed terbinafine OTC as a preferred product. Added tolnaftate as a preferred product. Administrative changes made to template.
6. October 15, 2019: Administrative update, added Oxistat lotion to the list of nonpreferred agents requiring prior authorization.
7. July 14, 2020: 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.

Provider Services