

## New Hampshire Medicaid Fee-for-Service Program

### Anti-Fungal Medication for Onychomycosis Criteria

Approval Date: January 22, 2024

#### Indications

Brand Names	Generic Names	Treatment
<b>Ciclodan</b> <sup>®</sup>	ciclopirox	Used as part of a comprehensive management program for topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement due to <i>Trichophyton rubrum</i> for patients ≥ 12 years old.
<b>Jublia</b> <sup>®</sup>	efinaconazole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> for patients ≥ 6 years old.
<b>Sporanox</b> <sup>®</sup>	itraconazole	Treatment of the following fungal infections in normal, predisposed, and immunocompromised patients: <ul style="list-style-type: none"> <li>• Cutaneous infections due to tinea corporis, tinea cruris, tinea pedis, and pityriasis versicolor when oral therapy is considered appropriate</li> <li>• Onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) for patients ≥ 18 years old</li> <li>• Invasive and noninvasive pulmonary aspergillosis</li> <li>• Oral and oral/esophageal candidiasis</li> <li>• Cutaneous and lymphatic sporotrichosis</li> <li>• Paracoccidioidomycosis</li> <li>• Chromomycosis</li> <li>• Blastomycosis</li> </ul>
<b>Kerydin</b> <sup>®</sup> (brand no longer available)	tavaborole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> for patients ≥ 6 years old.
<b>Lamisil</b> <sup>®</sup> (brand no longer available)	terbinafine	Treatment of onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) only for patients ≥ 12 years old.

## Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form	Administration
<b>Ciclodan®</b>	ciclopirox	8%	Topical solution	Fingernails and toenails: once daily application for 48 weeks
<b>Jublia®</b>	efinaconazole	10%	Topical solution	Toenails: once daily application for 48 weeks
<b>Sporanox®</b>	itraconazole	100 mg 100 mg/10mL	Capsule Oral Solution	Fingernails: Pulse therapy; 2 one-week courses of 200 mg BID for 7 days (28 caps) Toenails: 200 mg once daily for 12 weeks
<b>Kerydin®</b> (brand no longer available)	tavaborole	5%	Topical solution	Toenails: once daily application for 48 weeks
<b>Lamisil®</b> (brand no longer available)	terbinafine	250 mg	Tablet	Fingernails: 250 mg/day for 6 weeks Toenails: 250 mg/day for 12 weeks

## Criteria for Approval

1. Prior authorization (PA) will be granted if a patient meets the following conditions:
  - a. ciclopirox topical solution, terbinafine, Jublia® (efinaconazole), tavaborole:
    - i. Onychomycosis confirmed by a positive potassium hydroxide (KOH) stain, positive periodic acid–Schiff (PAS) stain, or a positive fungal culture, and experiencing pain that limits normal activity.
  - b. Sporanox® (itraconazole):
    - i. Approval will be granted for onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture and any of the following:
      1. Patient is experiencing pain which limits normal activity; **OR**
      2. Patient has an iatrogenically-induced or disease-associated immunosuppression; **OR**
      3. Patient has diabetes; **OR**
      4. Patient has significant peripheral vascular compromise.
    - ii. Approval will be granted for treatment of other fungal infections listed in the above indications.

Non-preferred drugs on the Preferred Drug List (PDL) require additional prior authorization (PA).

## Criteria for Denial

1. Prior approval will be denied if the criteria for approval are not met.
2. Prior approval will be denied for **cosmetic use**.

## Length of Approval

Brand Names	Generic Names	Length of Approval
Ciclodan®	ciclopirox	<ul style="list-style-type: none"> <li>• Initial: 3 months</li> <li>• Follow-up: 3 months (up to 1 year)</li> </ul>
Jublia®	efinaconazole	<ul style="list-style-type: none"> <li>• Toenail: 48 weeks</li> </ul>
Sporanox®	itraconazole	<ul style="list-style-type: none"> <li>• Fingernail: 8 weeks</li> <li>• Toenail: 12 weeks</li> </ul>
Kerydin® (brand no longer available)	tavaborole	<ul style="list-style-type: none"> <li>• Toenail: 48 weeks</li> </ul>
Lamisil® (brand no longer available)	terbinafine	<ul style="list-style-type: none"> <li>• Fingernail: 6 weeks</li> <li>• Toenail: 12 weeks</li> </ul>

## References

Available upon request.

## Revision History

Reviewed by	Reason for Review	Date Approved
Pharmacy and Therapeutic Committee	New	01/16/2003
Pharmacy and Therapeutic Committee	Update	03/24/2005
Commissioner	Approval	04/15/2005
Pharmacy and Therapeutic Committee	Update	11/06/2008
Commissioner	Approval	12/01/2008
DUR Committee	Revision	03/22/2010
Commissioner	Revision	04/30/2010
DUR Committee	Revision	06/18/2012
Commissioner	Revision	07/10/2012
	New drug to market	09/02/2014
DUR Board	New drug to market	05/12/2015
Commissioner	Approval	06/30/2015
DUR Board	Revision	10/24/2017
Commissioner	Approval	12/05/2017

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022
DUR Board	Revision	12/08/2023
Commissioner Designee	Approval	01/22/2024