

## New Hampshire Medicaid Fee-for-Service Program

### Anti-Fungal Medication for Onychomycosis Criteria

Approval Date: August 7, 2020

#### Indications

Brand Names	Generic Names	Treatment
	ciclopirox	As part of a comprehensive management program for the topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement due to <i>Trichophyton rubrum</i> .
Jublia®	efinaconazole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> .
Kerydin®	tavaborole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> .
Luzu®	luliconazole	Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by <i>Trichophyton rubrum</i> and <i>Epidermophyton floccosum</i> in patients ≥ two years old for Tinea corporis and patients ≥ 12 years old for Tinea cruris and Tinea pedis.
Onmel®	itraconazole	Treatment of onychomycosis of the toenail caused by <i>Trichophyton rubrum</i> or <i>Trichophyton mentagrophytes</i> .
Oxistat®	oxiconazole	Treatment of tinea pedis (can be used for both interdigital and plantar), tinea cruris, tinea corporis, and tinea versicolor (cream only).
Pedipak®	ciclopirox/urea	Topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails due to <i>Trichophyton rubrum</i> .
Sporanox®	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)</li> <li>▪ Invasive and noninvasive pulmonary aspergillosis</li> <li>▪ Oral and oral/esophageal candidiasis</li> </ul>

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Brand Names	Generic Names	Treatment
		<ul style="list-style-type: none"> <li>▪ Cutaneous and lymphatic sporotrichosis</li> <li>▪ Paracoccidioidomycosis</li> <li>▪ Chromomycosis</li> <li>▪ Blastomycosis</li> </ul>
	terbinafine	Treatment of onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) only.

## Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form	Administration
<b>Ciclodan<sup>®</sup></b>	ciclopirox	8%	Topical solution	Fingernails & toenails: once daily application
<b>CNL-8<sup>®</sup></b>	ciclopirox	8%	Topical solution	Fingernails & toenails: once daily application
<b>Jublia<sup>®</sup></b>	efinaconazole	10%	Topical solution	Toenails: once daily application for 48 weeks
<b>Kerydin<sup>®</sup></b>	tavaborole	5%	Topical solution	Toenails: once daily application for 48 weeks
	terbinafine	250 mg	Tablet	<ul style="list-style-type: none"> <li>▪ Fingernail: 250 mg/day for 6 weeks</li> <li>▪ Toenail: 250 mg/day for 12 weeks</li> </ul>
<b>Luzu<sup>®</sup></b>	Luliconazole	1%	Topical cream	<ul style="list-style-type: none"> <li>▪ Fingernails: once daily application for 2 weeks</li> <li>▪ Toenails: once daily application for 1 week</li> </ul>
<b>Onmel<sup>®</sup></b>	itraconazole	200 mg	Tablet	Toenail: 200 mg/day for 12 weeks
<b>Oxistat<sup>®</sup></b>	oxiconazole	1%	Cream/lotion	
<b>Pedipak<sup>®</sup></b>	ciclopirox/urea	8%/20%	8% nail lacquer topical solution (co-packaged with 20% urea cream)	<ul style="list-style-type: none"> <li>▪ Lacquer: once daily for 48 weeks</li> <li>▪ Cream: twice daily</li> </ul>
<b>Pedipirox<sup>®</sup> 4 Nail Kit</b>	ciclopirox	8%	Topical solution	
<b>Penlac<sup>®</sup> Nail Lacquer</b>	ciclopirox	8%	Topical solution	
<b>Sporanox<sup>®</sup></b>	itraconazole	100 mg 100 mg/10mL	Capsule Oral Solution	<ul style="list-style-type: none"> <li>▪ Fingernails: Pulse therapy; two one-week courses of 200 mg BID x 7 days (28 caps)</li> <li>▪ Toenails: Pulse therapy; two one-week courses of 200 mg BID x 7 days (28 caps)</li> </ul>

## Criteria for Approval

1. Prior authorization (PA) will be granted if a patient meets the following conditions:
  - a. terbinafine, Onmel<sup>®</sup> (itraconazole), Luzu<sup>®</sup> (luliconazole), Jublia<sup>®</sup> (efinaconazole), Kerydin<sup>®</sup> (tavaborole), Pedipak<sup>®</sup> (ciclopirox/urea):
    - i. Onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture, and experiencing pain that limits normal activity.
  - b. Sporanox<sup>®</sup> (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.
  - c. Ciclopirox topical solution:
    - i. Approval will be granted for onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture and patient is experiencing pain that limits normal activity.
    - ii. Approval will be granted only if the patient has failed an adequate treatment of both oral terbinafine and Sporanox<sup>®</sup> or has a contraindication for use of these agents.
2. 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
	ciclopirox	<ul style="list-style-type: none"> <li>▪ Initial: 3 months</li> <li>▪ Follow-up: 3 months (up to 1 year)</li> </ul>
<b>Jublia®</b>	efinaconazole	<ul style="list-style-type: none"> <li>▪ Toenail: 48 weeks</li> </ul>
<b>Kerydin®</b>	tavaborole	<ul style="list-style-type: none"> <li>▪ Toenail: 48 weeks</li> </ul>
<b>Luzu®</b>	luliconazole	<ul style="list-style-type: none"> <li>▪ Fingernail: 2 weeks</li> <li>▪ Toenail: 1 week</li> </ul>
<b>Onmel®</b>	itraconazole	<ul style="list-style-type: none"> <li>▪ Toenail: 12 weeks</li> </ul>
<b>Pedipak®</b>	ciclopirox/urea	<ul style="list-style-type: none"> <li>▪ Fingernail/toenail: 48 weeks</li> </ul>
<b>Sporanox®</b>	itraconazole	<ul style="list-style-type: none"> <li>▪ Fingernail: 8 weeks</li> <li>▪ Toenail: 12 weeks</li> </ul>
	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 & Therapeutic Committee	New	01/16/2003
Pharmacy & Therapeutic Committee	Update	03/24/2005
Commissioner	Approval	04/15/2005
Pharmacy & 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
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020