New Hampshire Medicaid Fee-for-Service Program

Anti-Fungal Medication for Onychomycosis Criteria

Approval Date: July 12, 2022

Indications

Brand Names	Generic Names	Treatment
Ciclodan®	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 *Trichophyton rubrum* for patients ≥ 12 years old.
Jublia®	efinaconazole	Treatment of onychomycosis of the toenail due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* for patients ≥ 6 years old.
Sporanox®	itraconazole	Treatment of the following fungal infections in normal, predisposed, and immunocompromised patients: • Cutaneous infections due to tinea corporis, tinea cruris, tinea pedis, and pityriasis versicolor when oral therapy is considered appropriate • Onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) for patients ≥ 18 years old • Invasive and noninvasive pulmonary aspergillosis • Oral and oral/esophageal candidiasis • Cutaneous and lymphatic sporotrichosis • Paracoccidioidomycosis • Chromomycosis • Blastomycosis
Kerydin®	tavaborole	Treatment of onychomycosis of the toenail due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* for patients ≥ 6 years old.
	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
Ciclodan®	ciclopirox	8%	Topical solution	Fingernails and toenails: once daily application for 48 weeks
Jublia®	efinaconazole	10%	Topical solution	Toenails: once daily application for 48 weeks
Sporanox®	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
Kerydin®	tavaborole	5%	Topical solution	Toenails: once daily application for 48 weeks
	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. terbinafine, Jublia® (efinaconazole), Kerydin® (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.

   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 itraconazole (Sporanox®) 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
Ciclodan®	ciclopirox	• Initial: 3 months • Follow-up: 3 months (up to 1 year)
Jublia®	efinaconazole	• Toenail: 48 weeks
Sporanox®	itraconazole	• Fingernail: 8 weeks • Toenail: 12 weeks
Kerydin®	tavaborole	• Toenail: 48 weeks
	terbinafine	• Fingernail: 6 weeks • Toenail: 12 weeks

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
DUR Board	Revision	03/12/2019

Reviewed by	Reason for Review	Date Approved
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