

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Topical Onychomycosis

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	Onychomycosis with no comorbidity or non- onychomycosis indications: One (1) year  Onychomycosis with relevant comorbidity: LIFETIME

Medications	Comments	Quantity Limit
ciclopirox 8% lacquer/solution ciclodan (ciclopirox) 8% solution	Preferred	May be subject to quantity limit
Ciclodan (ciclopirox) 8% Kit CNL 8 (ciclopirox) Kit Ciclopirox 8% Lacquer/Solution Kit Jublia (efinaconazole) Kerydin (tavaborole)	Non-Preferred	

***All products require prior authorization.***

***Non-Preferred products are further subject to step therapy with preferred products.***

### **APPROVAL CRITERIA**

#### **PRIOR AUTHORIZATION:**

Requests for topical agents for onychomycosis for individuals with **no relevant comorbidity** (normal immune system, and no disorder which predisposes to infection in the extremities) may be approved if:

- I. Jublia (efinaconazole) or Kerydin (tavaborole) is being used for onychomycosis of toenail;  
**OR**
- II. Ciclopirox Nail Lacquer/Solution is being used for onychomycosis of the toenail or fingernail;

**AND**

PAGE 1 of 3 08/27/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- III. Evidence of functional impairment (such as loss of one or more toenails, pain, or swelling) is present; **AND**
- IV. Individual has a confirmed fungal infection based on physical exam; **AND**
- V. Individual has one of the following:
  - A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to oral itraconazole or terbinafine; **OR**
  - B. Individual has a contraindication, drug interaction or concomitant clinical condition (such as but not limited to history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole or terbinafine unacceptable;

**OR**

- VI. Individual has used the requested topical product for onychomycosis within the previous 6 months.

Requests for topical agents for onychomycosis may be approved for individuals with a **relevant comorbidity** (abnormal immune system [i.e. HIV positive, on immunosuppressant drugs] and/or disorder which predisposes to infection in the extremities [i.e. Diabetes]), based on the following criteria:

- I. Jublia (efinaconazole) or Kerydin (tavaborole) is being used for onychomycosis of toenail; **OR**
- II. Ciclopirox Nail Lacquer/Solution is being used for onychomycosis of the toenail or fingernail;

**AND**

- III. Individual has a confirmed fungal infection based on physical exam; **AND**
- IV. Individual has one of the following:
  - A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to oral itraconazole or terbinafine; **OR**
  - B. Individual has a contraindication, drug interaction or concomitant clinical condition (such as but not limited to history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole or terbinafine unacceptable;

**OR**

- V. Individual has used the requested topical product for onychomycosis within the previous 6 months.

**STEP THERAPY:**

Requests for Ciclodan (ciclopirox) 8% Kit, CNL 8 (ciclopirox) Kit, Ciclopirox 8% Lacquer/Solution Kit, Jublia (efinaconazole), and Kerydin (tavaborole) must also meet the following criteria in addition to the above criteria:

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- I. Individual has had at least a 6 month trial (medication samples/coupons/discount cards are excluded from consideration as a trial) with inadequate response or intolerance to one preferred topical agent for onychomycosis; **OR**

Preferred Agents: ciclopirox 8% lacquer/solution, ciclofan 8% solution

- II. Individual has used the requested topical product for onychomycosis within the previous 6 months; **OR**
- III. The preferred agent is not FDA-approved for the prescribed indication.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.