### Market Applicability/Effective Date

| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|--------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | N/A | N/A | X | N/A | X | X | X | X | X | X | X | N/A | N/A | X |

*FHK- Florida Healthy Kids

---

## Topical Onychomycosis

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

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

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
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

his 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.

WEB-PEC-0674-17
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. 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.

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:

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, cicloidan 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.

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.
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.