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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**Key References:**


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.