UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number | 2019 P 2035-7
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Program | Prior Authorization/Medical Necessity – Topical Antifungals
Medication | Jublia, Kerydin
Effective Date | 8/1/2019; Oxford only: 8/1/2019

1. **Background:**
Jublia (efinaconazole) and Kerydin (tavaborole) are both indicated for the treatment of onychomycosis due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Presence of these organisms may be determined using molecular diagnostic testing. Fungal cultures require a longer turnaround time to obtain diagnosis.

2. **Coverage Criteria**:

A. **Jublia or Kerydin** will be approved based on **all** of the following criteria:

1. Submission of medical records (laboratory and clinical documentation) confirming diagnosis of onychomycosis of the toenail with one of the following infections (if request is for a subsequent course of therapy a new test must be performed):
   a. *Trichophyton rubrum*
   b. *Trichophyton mentagrophytes*

   **-AND-**

2. Treatment is requested due to medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, patients with diabetes who have additional risk factors for cellulitis, patients who experience pain/discomfort associated with the infected nail)

   **-AND-**

3. History of failure (subject to minimum treatment durations indicated below[^1^]), contraindication, or intolerance to **two** of the following antifungal agents (please document date of trial):
   a. Minimum of 12 week treatment with itraconazole (generic Sporanox)
   b. Minimum of 12 week treatment with oral terbinafine (generic Lamisil)

[^1^]: Minimum of 12 week treatment with itraconazole (generic Sporanox) and oral terbinafine (generic Lamisil), contraindication, or intolerance to **two** of the following antifungal agents.
c. Minimum of 12 week treatment with ciclopirox (generic Penlac)

Authorization will be issued for 48 weeks.

a. State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

b. For Connecticut and Kentucky business, only a 30 day trial will be required.

3. Additional Clinical Rules:
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. References:
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<th>Program</th>
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<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td><strong>Date</strong></td>
<td><strong>Change</strong></td>
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<tr>
<td>11/2014</td>
<td>New program</td>
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<tr>
<td>4/2015</td>
<td>Revised first line drugs to trial of 2 of 3 with addition of ciclopirox.</td>
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<tr>
<td>4/2016</td>
<td>Removed specified testing requirements. Added requirement for diagnosis of Trichophyton rubrum or Trichophyton mentagrophytes. Added minimum treatment durations to step 1 agents.</td>
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<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
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<tr>
<td>4/2018</td>
<td>Annual review. Updated references.</td>
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<tr>
<td>4/2019</td>
<td>Annual review. Revised documentation requirements. Updated references.</td>
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