

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3054-8
Program	Step Therapy – Topical Antifungals
Medication	Jublia, Kerydin
P&T Approval Date	4/2015, 4/2016, 4/2017, 4/2018, 4/2019, 4/2020
Effective Date	7/1/2020; Oxford only: N/A

**1. Background:**

Jublia (efinaconazole) and Kerydin (tavaborole) are both indicated for the treatment of onychomycosis due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes.

**2. Coverage Criteria<sup>a</sup>:**

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

1. History of failure (subject to minimum treatment durations indicated below<sup>b</sup>), 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)
  - c. Minimum of 12 week treatment with ciclopirox (generic Penlac)

**Authorization will be issued for 48 weeks.**

<sup>a</sup> 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.

<sup>b</sup> 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:**

1. Jublia Prescribing Information. Valeant Pharmaceuticals North Americal LLC. Bridgewater, NJ. September, 2016.
2. Terbinafine Prescribing Information. Dr. Reddy’s Laboratories Limited. Bachupally India. August 2012. .
3. Kerydin Prescribing Information. Anacor Pharmaceuticals, Inc., Palo Alto, CA. August 2018.
4. Treating Onychomycosis. Am Fam Physician. 2001 Feb 15;63(4):663-72, 677-8.
5. Sporanox Prescribing Information. Jansen Pharmaceuticals. Titusville, NJ. May 2018.
7. Penlac prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. June, 2016.

Program	Step Therapy – Topical Antifungals
<b>Change Control</b>	
<b>Date</b>	<b>Change</b>
4/2015	New program
4/2016	Added minimum treatment durations to step 1 agents
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2017	Updated references. State mandate reference language updated.
4/2018	Annual review. Updated references.
4/2019	Annual review. Revised documentation requirements. Updated references.
4/2020	Annual review. Updated references.