UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2035-11
Program	Prior Authorization/Medical Necessity – Topical Antifungals
Medication	Jublia® (efinaconazole) and Kerydin®* (tavaborole)
P&T Approval Date	11/2014, 4/2015, 4/2016, 4/2017, 4/2018, 4/2019, 4/2020, 4/2021, 4/2022, 10/2023
Effective Date	1/1/2024

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]:

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 of 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 after a minimum of 12 weeks of treatment[b], contraindication, or intolerance to **two** of the following antifungal agents (please document date of trial):

   a. itraconazole (generic Sporanox)
   b. oral terbinafine (generic Lamisil)
   c. 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 business, only a 60 day trial will be required. For 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.

*Brand Kerydin is typically excluded.

4. References:

1. Jublia [Package Insert]. Bridgewater, NJ: Bausch Health Companies Inc.; March 2022.
2. Kerydin [Package Insert]. Palo Alto, CA: Anacor Pharmaceuticals, Inc.; August 2018.
3. Treating Onychomycosis. Am Fam Physician. 2001 Feb 15;63(4):663-72, 677-8.
4. Goldstein AO. Onychomycosis: Management. UpToDate. September 2022. Accessed August 2023.
5. Grag J, Tilak R, Sanjay S, et al. Evaluation of Pan-Dermatophyte Nested PCR in Diagnosis of Onychomycosis. 2007. J Clin Microbiology. 45:3443-3445.

Program	Prior Authorization/Medical Necessity – Topical Antifungals
Change Control	
Date	**Change**
11/2014	New program
4/2015	Revised first line drugs to trial of 2 of 3 with addition of ciclopirox.
4/2016	Removed specified testing requirements. Added requirement for diagnosis of Trichophyton rubrum or Trichophyton mentagrophytes. Added minimum treatment durations to step 1 agents.
7/2016	Added Indiana and West Virginia 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.
4/2021	Annual review. Administrative change for reformatting and clarity. Updated references.
4/2022	Annual review. Corrected spelling of ciclopirox. State mandate reference language updated. Updated references.
10/2023	Annual review. Noted brand Kerydin is typically excluded. Updated references.