

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3054-12
Program	Step Therapy – Topical Antifungals
Medication	Jublia® (efinaconazole) and tavaborole
P&T Approval Date	4/2015, 4/2016, 4/2017, 4/2018, 4/2019, 4/2020, 4/2021, 4/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Jublia (efinaconazole) and 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^a:

A. **Jublia or tavaborole** will be approved based on the following criterion:

1. History of failure after a minimum 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, Kentucky and Mississippi 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 [Package Insert]. Bridgewater, NJ: Bausch Health Companies Inc.; March 2022.
2. Tavaborole [Package Insert]. bedminster, NJ: Alembic Pharmaceuticals, Inc.; December 2023.

3. Treating Onychomycosis. Am Fam Physician. 2001 Feb 15;63(4):663-72, 677-8.
4. Goldstein AO. Onychomycosis: Management. UpToDate. September 2022. Accessed September 5, 2024.

Program	Step Therapy – Topical Antifungals
Change Control	
Date	Change
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.
4/2021	Annual review. Administrative change for reformatting and clarity. Updated references.
4/2022	Annual review. State mandate reference language updated.
10/2023	Annual review. Noted brand Kerydin is typically excluded. Updated references.
10/2024	Removed references to brand Kerydin as it is no longer on the market. Updated CT/KY/MS state mandate footnote. Updated references.