

Initial Prior Authorization

Nail Antifungal, Topical

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Jublia	efinaconazole	topical solution
Kerydin	tavaborole	topical solution

Indications

FDA-approved Indications

Jublia

Jublia (efinaconazole) topical solution, 10% is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Kerydin

Kerydin (tavaborole) topical solution, 5% is an oxaborole antifungal indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Coverage Criteria

Onychomycosis of the Toenail(s)

Reference number(s)
1325-A

Authorization may be granted when the requested drug is being prescribed for onychomycosis of the toenail(s) due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* when the following criteria is met:

- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).

Duration of Approval (DOA)

- 1325-A: DOA: 12 months

References

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; March 2022.
2. Kerydin [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; August 2018.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).
5. Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: Rapid Evidence Review. American Academy of Family Physicians. 2021;104:359-368.

Document History

Written by: UM Development (CT)

Date Written: 06/2014

Revised: (MS) 05/2015, (NB) 12/2015 (modified from standard for plan design alignment as an option for clients who request modeling); (KM) 05/2016 (coverage criteria bullet one changed from "and" to "or"); (JH) 04/2017 (no clinical changes); (KC) 04/2018, (ME) 02/2019 (no clinical changes); (NZ) 02/2020 (no clinical changes); (KC) 12/2020 (no clinical changes); (PM) 09/2021 (no clinical changes); (MRS) 09/2022 (no clinical changes); (DRS) 09/2023 (no clinical changes); (DFW) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (LMS) 06/2014; (KU) 05/2015, (AD) 01/2016; (ME) 05/2016; (CHART) 02/27/20, 12/31/20, 09/30/21, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 07/2014, 10/2015, 02/2016, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020, 04/2021, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for onychomycosis of the toenail(s) due to <i>Trichophyton rubrum</i> or <i>Trichophyton mentagrophytes</i> ? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient's diagnosis been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for a specific fungal infection of your toenail(s). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Approve, 12 Months	Deny	<p>Your plan only covers this drug when you have a fungal diagnostic test. We denied your request because we did not receive your results, or your test result did not show a positive test result. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test]</p>