

Initial Prior Authorization with Quantity Limit Kerydin

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
Kerydin	tavaborole	topical solution

Indications

FDA-approved Indications

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)

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 ALL of the following criteria are met:

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

Reference number(s)
1169-C

- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)
 - The patient has experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)
 - The patient has a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)
- The requested drug is NOT being used in a footbath
- If additional quantities are required, multiple toenails are being treated

Quantity Limits Apply

Treatment of a single nail: 4 mL per 21 days or 12 mL per 63 days

Treatment of multiple nails: 20 mL per 21 days or 60 mL per 63 days

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

Duration Of Approval (DOA)

- 1169-C: DOA: 12 months

References

1. Kerydin [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; August 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed August 7, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/07/2023).
4. Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: Rapid Evidence Review. American Academy of Family Physicians. 2021;104:359-368.
5. Centers for Disease Control (CDC) and Prevention. Fungal Nail infections. Available at: <https://www.cdc.gov/fungal/nail-infections.html>. Accessed August 7, 2023.
6. Lipner SR, Scher RK. Efinaconazole in the treatment of onychomycosis. Infect Drug Resist. 2015;8:163-172.