



Reference number(s)
1160-C

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# Initial Prior Authorization with Quantity Limit Jublia

## 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
Jublia	efinaconazole

## Indications

### FDA-approved Indications

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*.

## 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:

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- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
- 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 toenail: 4 mL per 21 days or 12 mL per 63 days

Treatment of multiple toenails: 16 mL per 21 days or 48 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)

- 1160-C: DOA: 12 months

## References

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; March 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).
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. Treatment of Ringworm and Fungal Nail infections. Available at: <https://www.cdc.gov/ringworm/treatment/index.html>. Accessed September 10, 2024.