

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

JUBLIA
(efinaconazole topical solution)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for onychomycosis of the toenail(s) due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*

AND

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

AND

- The patient has experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)

OR

- The patient has experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)

OR

- The patient has a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)

AND

- The requested drug is not being used in a footbath

AND

- If additional quantities are required, multiple toenails are being treated

Quantity Limits Apply.

4 mL/21 days* or 12 mL/63 days*

Additional Quantities: 16 mL/21 days* or 48 mL/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.*

REFERENCES

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; July 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed December 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2020.
4. Elewski BE, Rich P, Pollak R, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis: Two phase III multicenter randomized, double-blind studies. *J Am Acad Dermatol* 2013;68:600-8.
5. Kreijkamp-Kaspers S, Hawke K, Guo L, et al. Oral antifungal medication for toenail onychomycosis. Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD010031. Accessed December 2020.

6. Centers for Disease Control (CDC) and Prevention. Fungal Nail infections. <https://www.cdc.gov/fungal/nail-infections.html>. Accessed December 2020.
7. Lipner SR, Scher RK. Efinaconazole in the treatment of onychomycosis. *Infect Drug Resist.* 2015;8:163–172.