

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.

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

Treatment of multiple nails: 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.

REFERENCES

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; March 2022.
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3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed July 17, 2022.
4. Kreijkamp-Kaspers S, Hawke K, Guo L, et al. Oral antifungal medication for toenail onychomycosis. *Cochrane Database Syst Rev*. 2017;7:CD010031.
5. Centers for Disease Control (CDC) and Prevention. Fungal Nail infections. <https://www.cdc.gov/fungal/nail-infections.html>. Accessed July 29, 2022.

6. 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;68:600-608.
7. Lipner SR, Scher RK. Efinaconazole in the treatment of onychomycosis. *Infect Drug Resist*. 2015;8:163–172.