
Prior Authorization DRUG Guidelines

Jublia (efinaconazole)

Effective Date: 8/18/2020

Date Developed: 8/18/2020 by Dr. H. Taekman

Last Approval Date: 8/18/2020, 2/2/21, 8/3/21, 2/1/22,
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Jublia is an azole antifungal that inhibits fungal lanosterol 14alpha-demethylase involved in the biosynthesis of ergosterol, a constituent of fungal cell membranes, resulting in fungal cell death.

Authorization Criteria: Topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. **Note:** For patients with distal subungual onychomycosis involving ≤50% of the nail and sparing the matrix/lunula

Jublia will be approved based on all of the following criteria:

1. Submission of medical records (laboratory and clinical documentation) confirming diagnosis of onychomycosis of the toenail with of one of the following infections (if request is for a subsequent course of therapy a new test must be performed):

- a. *Trichophyton rubrum*
- b. *Trichophyton mentagrophytes*

NOTE: . Presence of these organisms may be determined using molecular diagnostic testing. Fungal cultures require a longer turnaround time to obtain diagnosis.

-AND-

2. Treatment is requested due to medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, patients with diabetes who have additional risk factors for cellulitis, patients who experience pain/discomfort associated with the infected nail)

-AND-

3. History of failure (subject to minimum treatment durations indicated below), contraindication, or intolerance to **two** of the following antifungal agents (please document date of trial):

- a. Minimum of 12-week treatment with itraconazole (generic Sporanox)
- b. Minimum of 12-week treatment with oral terbinafine (generic Lamisil)
- c. Minimum of 12-week treatment with ciclopirox (generic Penlac)

Dose: Apply to affected toenail(s) once daily for 48 weeks; ensure complete coverage of the toenail, the toenail folds, toenail bed, surrounding skin, and the undersurface of the toenail plate

References:

1. *Jublia (efinaconazole) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; July 2020.*
2. *Lipner SR, Scher RK. Efinaconazole in the treatment of onychomycosis. Infect Drug Resist. 2015;8:163-172.*
3. *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(4):600-608.*
4. *Kaul S, Yadav S, Dogra S. Treatment of dermatophytosis in elderly, children, and pregnant women. Indian Dermatol Online J. 2017;8(5):310-318.*

Revision History:

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
8/18/20	New	Howard Taekman, MD	New
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Added References
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated definition of Jublia and authorization criteria