

PR I O R AUTH O R I ZATI O N CR I T E R I A

BRAND NAME*
(generic)

JUBLIA
(efinaconazole topical solution)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 1160- A

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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*, which 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)

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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*. Jublia is to be applied to affected toenails once daily for 48 weeks, using the integrated flow-through brush applicator. When applying Jublia, the toenail, the toenail folds, toenail bed, hyponychium, and the under surface of the toenail plate are to be completely covered.

Onychomycosis may be diagnosed by the presence of fungi by culture, microscopy (Potassium hydroxide [KOH] stain), or histological examination of the nail plate.⁵ Microscopy is a commonly used method because it is inexpensive and easy to perform; nail clippings or scrapings are placed in a drop of KOH and examined under a microscope for the presence of fungal elements.⁶

Per the CDC, oral antifungal therapy (terbinafine) is considered first line treatment for confirmed onychomycosis.⁶ According to the Cochrane review, medication taken orally appears to cure the condition more quickly and effectively than topical treatment. There was high-quality evidence that oral azole (itraconazole) and terbinafine treatments were more effective for achieving mycological cure and clinical cure for onychomycosis compared to placebo, and when compared directly, terbinafine was probably more effective than azoles and likely not associated with excess adverse events (griseofulvin was associated with more adverse reactions than azoles and terbinafine).⁵ Oral treatment of onychomycosis is the standard of care, however, drug interactions and risk of acute liver injury can limit their use.⁴ Difficulties in

for mutating topical treatment to penetrate the nail and reach the site of infection in the nail bed has hampered the development and the use of topical agents.⁴ Jublia is the first triazole antifungal developed for the treatment of onychomycosis. In 2 randomized trials, complete cure rate, defined as no evidence of fungal infection at week 52, was demonstrated in 15.2% to 17.8% of patients receiving efinaconazole (N=1236) compared with 3.3% to 5.5% receiving placebo (N=415) for the treatment of onychomycosis of the toenail. Jublia provided an effective and well-tolerated treatment and may be the first topical treatment that can be considered a viable alternative to oral treatments.⁴

REFERENCES

1. Jublia [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2016.
2. Lexi-Comp Online, AHFS Drug Information (Adult and Pediatric) Online. Hudson, OH: Walters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com>. Accessed February 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com>. Accessed February 2020.
4. Bewske 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. Krejlikamp-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 February 2020.
6. Centers for Disease Control (CDC) and Prevention. Fungal Nail Infections. <https://www.cdc.gov/fungal/nail-infections.html>. Accessed February 2020.

Written by: UM Development (CT)
 Date Written: 06/2014
 Revised: (MS) 05/2015; (KM) 05/2016; (JH) 04/2017 (no clinical changes); (KC) 04/2018 (no clinical changes); (ME) 02/2019 (no clinical changes); (PM) 02/2020 (removed MDC designation)
 Reviewed: Medical Affairs (LMS) 06/2014; (KU) 05/2015; (ME) 05/2016; (CHART) 02/27/20
 External Review: 07/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes, which has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)?	Yes	No
2	Has the patient experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)?	Yes	No
3	Has the patient experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)?	Yes	No
4	Does the patient have a contraindication that would prohibit initiation of an oral antifungal therapy (e.g., terbinafine, itraconazole)?	Yes	No

Guidelines for Approval					
Duration of Approval: 12 Months					
Set 1		Set 2		Set 3	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	1	2	1	2
2		3		4	3

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Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You have a specific fungal infection of the toenail(s) - You had a test to confirm your toenail fungal infection Your request has been denied based on the information we have. [Short Description: No approved diagnosis, no confirmation of diagnosis]
2.	Approve, 12 months	Go to 3	
3.	Approve, 12 months	Go to 4	
4.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an oral antifungal medicine first and it did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to oral antifungal]