PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

JUBLIA
(efinaconazole topical solution)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 1160-C***

**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

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.

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.[1-3]

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 formulating 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]

The prior authorization criteria do not approve Jublia for use in a footbath, as this is not an FDA-approved use. Jublia is for topical use only and not for oral, ophthalmic, or intravaginal use.[1]

Jublia is available as a solution supplied in 4 mL and 8 mL bottles.[1] 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 undersurface of the toenail plate are to be completely covered. Apply one drop of Jublia onto the toenail. For the big toenail, also apply a second drop to the end of the toenail using the tip of the brush.[1]

While not published by manufacturer, judging from patient use, there are approximately 80 drops in a 4 mL bottle.[7] Therefore, if the patient has an infection that requires less than or equal to 3 drops per day, then the initial limit of 4 mL is approximately sufficient for a 28 day period. For example: A patient with an infection of one big toenail and one other toenail requires:

- 2 drops to the big toenail daily = 2 drops X 28 days = 56 drops per 28 days
- 1 drop to any other toenail daily = 1 drop X 28 days = 28 drops per 28 days

For a total of approximately 84 drops per 28 days.

If the patient has an affected area that requires more than 4 mL per month, additional criteria will apply.

The PA allows for additional quantities if the patient requires treatment of onychomycosis affecting multiple toenails. The PA allows for a quantity approximately sufficient to treat an infection of all toenails. The quantity allowed upon approval of PA is approximately sufficient to allow treatment of two big toenails daily (112 drops, or 5.6 mL, per 28 days) and eight other toenails daily (224 drops, or 11.2 mL, per 28 days). Therefore, the quantity for patients requiring treatment of multiple toenails will be set at 16 mL per 28 days.

REFERENCES

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; July 2020.
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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.

Written by: UM Development (CT)
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes? [If no, then no further questions.]	Yes	No
2	Has the patient's diagnosis been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)? [If no, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If yes, then skip to question 6.]	Yes	No
4	Has the patient experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If yes, then skip to question 6.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If no, then no further questions.]	Yes	No
6	Is the requested drug being used in a footbath? [If yes, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 4 mL per month? [Note: If higher quantities are needed, additional questions are required.] [If no, then no further questions.]	Yes	No
8	Are multiple toenails being treated? [If no, then no further questions.] [RPh Note: If no, then deny and enter a partial approval for 4 mL / 21 days or 12 mL / 63 days.]	Yes	No
9	Does the patient require MORE than the plan allowance of 16 mL per month? [RPh Note: If yes, then deny and enter a partial approval for 16 mL / 21 days or 48 mL / 63 days.]	Yes	No

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 have a specific fungal infection of the toenail(s). Your request has been denied based on the information we have.

			[Short Description: No approvable diagnosis]
2.	Go to 3	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 confirmation of diagnosis]
3.	Go to 6	Go to 4	
4.	Go to 6	Go to 5	
5.	Go to 6	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 antifungals]
6.	Deny	Go to 7	You do not meet the requirements of your plan. Your plan covers this drug when it is not being used in a footbath. Your request has been denied based on the information we have. [Short Description: Used in footbath]
7.	Go to 8	Approve, 12 months, 4 mL/21 days* or 12 mL/63 days*	
8.	Go to 9	Deny	You do not meet the requirements of your plan. Your plan covers additional quantities of this drug when multiple toenails are being treated. Current plan approved criteria cover up to 4 mL per month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 12 months. Your request for additional quantities has been denied based on the information we have. [Short Description: Not enough area affected]
9.	Deny	Approve, 12 months, 16 mL/21 days* or 48 mL/63 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 16 mL per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**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.*