Reference number(s)
1160-C

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Initial Prior Authorization with Quantity Limit
Jublia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Jublia	efinaconazole

Indications

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

Onychomycosis of the Toenail(s)

Authorization may be granted when the requested drug is being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes when ALL of the following criteria are met:

- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to an oral antifungal therapy (e.g., terbinafine, itraconazole).
    - The patient has experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole).
    - The patient has a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole).
- The requested drug is NOT being used in a footbath.
- If additional quantities are required, multiple toenails are being treated.

Quantity Limits Apply

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

Treatment of multiple toenails: 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.

Duration Of Approval (DOA)

- 1160-C: DOA: 12 months

References

1. Jublia [package insert]. Bridgewater, NJ: Bausch Health US LLC; March 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed September 10, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/10/2024).
4. Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: Rapid Evidence Review. American Academy of Family Physicians. 2021;104:359-368.
5. Centers for Disease Control (CDC) and Prevention. Treatment of Ringworm and Fungal Nail infections. Available at: https://www.cdc.gov/ringworm/treatment/index.html. Accessed September 10, 2024.

Reference number(s)
1160-C

Document History

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); (KC) 12/2020 (added footbath question, limit); (PM) 09/2021 (no clinical changes); (TR/MRS) 09/2022 (no clinical changes); (DRS) 09/2023 (no clinical changes); (JL/DFW) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (LMS) 06/2014; (KU) 05/2015; (ME) 05/2016; (CHART) 02/27/20, 12/31/20, 09/30/21, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 07/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020, 04/2021, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes? [If Yes, then go to 2. 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 Yes, then go to 3. 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 go to 6. If No, then go to 4.]	Yes	No
4	Has the patient experienced an intolerance to an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If Yes, then go to 6. If No, then go to 5.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of an oral antifungal therapy (e.g., terbinafine, itraconazole)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is the requested drug being used in a footbath? [If Yes, then no further questions. If No, then go to 7.]	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.]	Yes	No

[If Yes, then go to 8. If No, then no further questions.]

8 Are multiple toenails being treated? Yes No
[If Yes, then go to 9. 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.

9 Does the patient require MORE than the plan allowance of 16 mL per month? Yes No
[No further questions]

RPH Note: If yes, then deny and enter a partial approval for 16 mL / 21 days or 48 mL / 63 days.

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for a specific fungal infection of your toenail(s). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug when you have a fungal diagnostic test. We denied your request because we did not receive your results, or your test result did not show a positive test result. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Lab/test]

3.	Go to 6	Go to 4	
4.	Go to 6	Go to 5	
5.	Go to 6	Deny	Your plan only covers this drug if you have tried an oral antifungal therapy (e.g., terbinafine, itraconazole), and it did not work well for you. We have denied your request because: A) You have not tried it, or B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
6.	Deny	Go to 7	Your plan only covers this drug if it is not being used in a footbath. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Footbath Use]
7.	Go to 8	[PA Approved for 12 months. Approve 4 mL/21 days or 12 mL/63 days]. Approve, 12 Months	
8.	Go to 9	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers

			more of this drug (additional quantities) when you meet the criteria for additional quantities. We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (4 mL per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met, Partial denial]
9.	Deny	[Approve PA for 12 months. Approve 16 mL/21 days or 48 mL/63 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (16 mL per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]