

## **Clinical Policy: Efinaconazole (Jublia)**

Reference Number: CP.PMN.25

Effective Date: 08.01.16

Last Review Date: 02.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Efinaconazole (Jublia<sup>®</sup>) is an azole antifungal.

### **FDA Approved Indication(s)**

Jublia is indicated for the topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Jublia is **medically necessary** when the following criteria are met:

## **I. Initial Approval Criteria**

### **A. Onychomycosis (must meet all):**

1. Diagnosis of onychomycosis of the toenails;
2. Age  $\geq$  6 years;
3. If age  $\geq$  18 years, member meets one of the following (a or b):
  - a. Failure of a 12-week trial of oral terbinafine at up to maximally indicated doses within the past 12 months;
  - b. Member has intolerance or contraindicated to oral terbinafine, and failure of ciclopirox 8% topical solution, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 8 mL per 30 days.

**Approval duration: 48 weeks**

### **B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## **II. Continued Therapy**

### **A. Onychomycosis (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 8 mL per 30 days.

**Approval duration: 48 weeks**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 48 weeks (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
terbinafine (Lamisil®)	Toenail onychomycosis: 250 mg PO once daily for 12 weeks	250 mg/day
ciclopirox 8% topical solution (Penlac®)	Apply once daily (preferably at bedtime or eight hours before washing) to all affected nails with the applicator brush provided. Daily applications should be made over the previous coat and removed with alcohol every seven days. This cycle should be repeated throughout the duration of therapy. The safety and efficacy of using ciclopirox daily for > 48 weeks have not been established.	See dosing regimen

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Onychomycosis	Apply to affected toenails once daily for 48 weeks	Once daily

**VI. Product Availability**

Solution: 10%

**VII. References**

1. Jublia Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2020. Available at <http://www.jubliarx.com/>. Accessed May 18, 2020.
2. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-70.
3. Lamisil Tablets Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/020539s033lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020539s033lbl.pdf). Accessed October 28, 2019.
4. Ciclopirox Prescribing Information. South Plainfield, NJ: G&W Laboratories, Inc.; March 2015. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3ef301b7-c40a-0635-4a76-185141473dba>. Accessed October 15, 2019.
5. Gupta AK, Daigle D, and Foley KA. Network meta-analysis of onychomycosis treatments. Skin Appendage Disorder. 2015; 1: 74-81.
6. Gupta AK, Foley KA, Mays RR, Shear NH, and Piguet V. Monotherapy for toenail onychomycosis: a systematic review and network meta-analysis. British Journal of Dermatology. 2019. DOI 10.1111/bjd.18155
7. Ameen M, Lear JT, Madan V, Mustapa MF, and Richardson M. British Association of Dermatologists' guidelines for management of onychomycosis 2014. British Journal of Dermatology. 2014; 171: 937-958.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy.	06.16	08.16
Converted to new template. Initial: removed age requirement as not an absolute contraindication per PI; modified duration of trial of terbinafine from 3 months to 12-weeks per Lamisil PI and American Family Physician. Added documentation of positive response to therapy on re-auth. Modified generalized FDA approved max recommended dose to specific QL statement. Updated references.	03.17	08.17
1Q18 annual review: - Policies combined for Centene Medicaid and Commercial lines of business.	11.03.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<ul style="list-style-type: none"> <li>- Added age restriction as safety and effectiveness in pediatrics have not been established; specified a timeframe of within the past 12 months for oral terbinafine trial;</li> <li>- Commercial: specified duration of trial of oral terbinafine for toenail onychomycosis per PI; added QL.</li> <li>- Medicaid: Removed laboratory testing related to confirmation of fungal infection; re-auth: removed requirement that member has not used Jublia daily <math>\geq 48</math> weeks as this would be difficult to verify objectively; modified approval duration from “up to 48 weeks total” to 48 weeks.</li> <li>- References reviewed and updated.</li> </ul>		
1Q 2019 annual review: no significant change from previously approved policy; references reviewed and updated.	09.27.18	02.19
1Q 2020 annual review: added HIM line of business, retired HIM.PA.25; added (for Commercial/Medicaid)/modified (for HIM) requirement for ciclopirox 8% topical solution failure if member has intolerance or contraindication to oral terbinafine; references reviewed and updated.	10.28.19	02.20
RT4 policy update: lowered the covered age limit from 18 years to $\geq 6$ years of age based on a label update supporting use in pediatrics; references reviewed and updated.	05.18.20	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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