

Clinical Policy: Efinaconazole (Jublia)

Reference Number: CP.PMN.25

Effective Date: 08.01.16

Last Review Date: 02.21

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[®]) 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[®] 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.PA.154 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.PA.154 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.PA.154 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
terbinafine (Lamisil [®])	Toenail onychomycosis: 250 mg PO QD 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 November 17, 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. Accessed November 17, 2020.
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 November 17, 2020.
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
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. - 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;	11.03.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<ul style="list-style-type: none"> - Commercial: specified duration of trial of oral terbinafine for toenail onychomycosis per PI; added QL. - Medicaid: Removed laboratory testing related to confirmation of fungal infection; re-auth: removed requirement that member has not used Jublia daily ≥ 48 weeks as this would be difficult to verify objectively; modified approval duration from “up to 48 weeks total” to 48 weeks. - References reviewed and updated. 		
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 ≥ 6 years of age based on a label update supporting use in pediatrics; references reviewed and updated.	05.18.20	
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.17.20	02.21

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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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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