Clinical Policy: Efinaconazole (Julia)

Reference Number: CP.PMN.25
Effective Date: 08.01.16
Last Review Date: 02.19
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Efinaconazole (Julia®) is an azole antifungal.

FDA Approved Indication(s)

Julia is indicated for the topical treatment of onychomycosis of the toenails 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 Julia 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 ≥ 18 years;
3. Failure of a 12-week trial of oral terbinafine at up to maximally indicated doses within the past 12 months, 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 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 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 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 once daily for 12 weeks	250 mg/day

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; September 2016. Available at http://www.jubliarx.com/. Accessed September 27, 2018.
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; January 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed September 27, 2018.

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. - 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; - 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.	11.03.17	02.18
1Q 2019 annual review: no significant change from previously approved policy; references reviewed and updated.	09.27.18	02.19

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.