Clinical Policy: Efinaconazole (Julia)

Reference Number: ERX.NPA.147
Effective Date: 09.01.20
Last Review Date: 02.22
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 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 6 years;
3. If age ≥ 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 contraindication 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not received more than 48 weeks of treatment with Julia;
4. If request is for a dose increase, new dose does not exceed 8 mL per 30 days.

Approval duration: up to 48 weeks of total treatment

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 48 weeks (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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
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 September 22, 2021.
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: Cosette Pharmaceuticals, Inc.; November 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3ef301b7-c40a-0635-4a76-185141473dba. Accessed September 21, 2021.

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
Policy created	05.18.20	08.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.17.20	02.21
1Q 2022 annual review: for continued therapy added criteria to ensure member has not received more than 48 weeks of treatment; modified approval duration to allow up to 48 weeks of total treatment per prescribing information; references reviewed and updated.	09.21.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.