RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	efinaconazole
Policy Number:	RxA.607
Drug(s) Applied:	Jublia®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Efinaconazole (Jublia®) is an azole antifungal.
Jublia® is indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
efinaconazole (Jublia®)	Onychomycosis	Apply to affected toenails once daily for 48 weeks	Once daily

Dosage Forms

- Solution: 10%

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of onychomycosis of the toe nails;
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
Commercial: 48 weeks
Medicaid: 48 weeks

II. Continued Therapy Approval

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

1. Member is currently receiving the medication that has been authorized by RxAdvance or member

has met initial approval criteria listed in this policy;
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
Commercial: 48 weeks
Medicaid: 48 weeks

III. Appendices

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
- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information
- Efinaconazole is an azole antifungal. Efinaconazole inhibits fungal lanosterol 14α-demethylase involved in the biosynthesis of ergosterol, a constituent of fungal cell membranes.

References
1. Jublia Prescribing Information. Bridgewater, Bausch Health Companies Inc. Canada; July 2020. Available at http://www.jubliarx.com/. Accessed September 4, 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; January 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed September 4 , 2020.
4. Goldstein AO. Onychomycosis: Management. August 2020. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020. Accessed with subscription at: http://uptodate.com. Accessed September 15, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020

Policy was reviewed: 1. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance...” 2. Appendix D General information added. 3. References was reviewed and updated.	9/04/2020	12/07/2020