

Clinical Policy Title:	efinaconazole
Policy Number:	RxA.607
Drug(s) Applied:	Jublia®
Original Policy Date:	03/06/2020
Last Review Date:	03/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Onychomycosis (must meet all):

1. Diagnosis of onychomycosis of the toenails;
2. For patients age \geq 18 years, trial and failure of a 12-week course of oral terbinafine at a maximum daily dose of 250 mg within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced;

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Onychomycosis (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;
2. Member has not received more than 12 months of treatment with Jublia®.

Approval duration

All Lines of Business (except Medicare): up to 12 months of total treatment

References

1. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-770. Available at: <https://pubmed.ncbi.nlm.nih.gov/24364524/>. Accessed August 30, 2022.
2. Goldstein AO. Onychomycosis: Management. 2022. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020. Available at: <http://uptodate.com>. Accessed August 30, 2022.

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance...” Appendix D General information added. References was reviewed and updated. 	<p>9/04/2020</p>	<p>12/07/2020</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. Initial and Continued approval duration was updated from 48 weeks to 12 months. Initial Approval Criteria I.A.2 age criteria was updated from “≥ 18 years of age” to “≥ 6 years of age”. Therapeutic Alternatives was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". References were reviewed and updated. 	<p>10/13/2021</p>	<p>12/7/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Initial Approval Criteria I.A.3: Added patients age ≥ 18 years, trial and failure of a 12-week course of oral terbinafine at a maximum daily dose of 250 mg within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced. Continued therapy approval II.A.3: added member has not received more 	<p>08/30/2022</p>	<p>10/19/2022</p>

<p>than 12 months of treatment with Jublia®.</p> <p>3. Continued therapy approval duration was updated to up to 12 months of total treatment from 12 months.</p> <p>4. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>11/20/2023</p>	<p>11/20/2023</p>
<p>Policy updated:</p> <p>1. Removed QL</p>	<p>3/1/2024</p>	<p>2/28/2024</p>