Topical Antifungals

Description

Jublia (efinaconazole), Kerydin (tavaborole)

Background
Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi that occurs under the toenail. Jublia and Kerydin are both antifungal solutions used topically to treat onychomycosis of the toenails caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Oral treatment of onychomycosis is the standard of care, however, drug interactions and risk of acute liver injury can limit their use (1-3).

Regulatory Status
FDA-approved indications:

**Jublia** is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* (1).

**Kerydin** is an oxaborole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* (2).

Safety and effectiveness of Jublia in pediatric patients have not been established. Safety and effectiveness of Kerydin in pediatric patients below 6 years of age have not been established (1-2).

Related policies
Ecoza, Ertaczo, Exelderm, Luzu, Oxistat
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jublia and Kerydin may be considered medically necessary in patients 18 years of age and older for Jublia and patients 6 years of age and older for Kerydin with onychomycosis of the toenails and if the conditions indicated below are met.

Jublia and Kerydin are considered investigational for all other ages and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older for Jublia ONLY
6 years of age and older for Kerydin ONLY

Diagnosis

Patient must have the following:

Onychomycosis of the toenail(s)

AND ALL of the following:
1. Laboratory and clinical documentation of ONE of the infections:
   a. Trichophyton rubrum
   b. Trichophyton mentagrophytes
2. Inadequate treatment response, intolerance, or contraindication to a legend oral or topical antifungal therapy

Prior – Approval Renewal Requirements
None

Policy Guidelines
Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits

None

Rationale

Summary

Jublia and Kerydin are both antifungal solutions used to topical treat onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Safety and effectiveness of Jublia in pediatric patients have not been established. Safety and effectiveness of Kerydin in pediatric patients below 6 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Jublia and Kerydin while maintaining optimal therapeutic outcomes.

References


Policy History

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<td>December 2014</td>
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Keywords
Section: Prescription Drugs		Effective Date: October 1, 2019
Subsection: Topical Products		Original Policy Date: January 1, 2015
Subject: Topical Antifungals		Page: 4 of 4

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.