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 and Kerydin in pediatric patients have not been established (1-2).

Related policies

Ecoza, Ertaczo, Exelderm, Luzu, Oxistat
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 or older with onychomycosis of the toenails and if the conditions below are met.

Jublia and Kerydin are considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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 and Kerydin in pediatric patients 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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2014</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2016</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.14.09 to 5.90.09</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td></td>
<td>Addition of legend to the T/F statement</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.