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5.90.009

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	January 1, 2015
Subject:	Topical Antifungals	**Page:**	1 of 4

Last Review Date: September 6, 2024

Topical Antifungals

Description

Jublia (efinaconazole), Kerydin (tavaborole)

Background
Onychomycosis is a fungal infection of the nails caused predominantly by dermatophytes of the genus *Trichophyton*. Jublia (efinaconazole) and Kerydin (tavaborole) are both antifungal solutions used topically to treat onychomycosis of the toenails caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Accurate diagnosis is crucial for successful treatment and requires identification of physical changes and positive laboratory analysis. Only half of all nail problems are caused by onychomycosis, and diagnosis by physical examination alone can be inaccurate. Treatment varies depending on the severity of the condition, as well as the causative organism and concerns about adverse effect and drug interactions (1-3).

Regulatory Status
FDA-approved indications:
Jublia is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) 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 daily use of Jublia or Kerydin for longer than 48 weeks have not been established (1-2).

Safety and effectiveness of Jublia and Kerydin in pediatric less than 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** if the conditions indicated below are met.

Jublia and Kerydin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 years of age and 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 prescription oral therapy (e.g., terbinafine, itraconazole, griseofulvin)
3. Inadequate treatment response, intolerance, or contraindication to a topical antifungal therapy (e.g., ciclopirox)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity Limit

Medication	Quantity
Jublia 4 mL	16 mL per 84 days **OR**
Jublia 8 mL	
Kerydin 4 mL	20 mL per 84 days
Kerydin 10 mL	

Duration 12 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Jublia (efinaconazole) and Kerydin (tavaborole) are both antifungal topical solutions used for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Safety and effectiveness of daily use of Jublia or Kerydin for longer than 48 weeks have not been established. Safety and effectiveness of Jublia and 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

1. Jublia [package Insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2022.
2. Kerydin [package Insert]. Melville, NY: Anacor Pharmaceuticals, Inc.; August 2018.
3. Westerberg, D & Voyack, M. Bassler M. Onychomycosis: Current Trends in Diagnosis and Treatment. American Family Physician 2013 Dec 1;88 (11):762-770.

Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual editorial review and reference update
December 2016	Annual editorial review and reference update Policy number change from 5.14.09 to 5.90.09
September 2017	Annual editorial review and reference update Addition of legend to the T/F statement
August 2018	Change in age limit from 18 years and older for Kerydin to 6 years and older
September 2018	Annual review and reference update
November 2018	Annual review and reference update
September 2019	Annual review
May 2020	Reduced age requirement for Jublia from 18 and older to 6 and older
June 2020	Annual review
March 2021	Reference update. Revised T/F requirement to require T/F, intolerance, or contraindication to both prescription oral and another topical antifungal. Added quantity limit for both Jublia and Kerydin
June 2021	Annual review
December 2022	Annual review and reference update. Changed policy number to 5.90.009
December 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.