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DRUG POLICY

Jublia and Kerydin

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Jublia and Kerydin prior authorization policy is to ensure appropriate selection of patients based on product labeling and/or clinical guidelines and/or clinical studies, and to encourage the use of more cost-effective agents prior to the use of Jublia or Kerydin for the treatment of onychomycosis.

Jublia (efinaconazole) and **Kerydin** (tavaborole) are both indicated for the topical treatment of onychomycosis of toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- I. Laboratory testing results confirming diagnosis and fungal etiology (e.g., positive potassium hydroxide [KOH] stain, fungal culture or nail biopsy).

Criteria for Approval

- I. **Jublia** and **Kerydin** topical treatment may be considered **medically necessary** for the treatment of onychomycosis when ALL the following criteria are met:
 - Diagnosis is distal lateral subungual onychomycosis of the toenail, fungal etiology has been confirmed by appropriate laboratory testing (e.g., positive potassium hydroxide [KOH] stain, fungal culture or nail biopsy); AND
 - 50% or less clinical involvement of target toenail(s) with no lunula involvement or dermatophytomas present
 - Treatment is requested due to a medical condition and NOT for cosmetic purposes (e.g., immunocompromised patients, patients with history of cellulitis of the lower extremity, patients

with diabetes and additional risk factors for cellulitis, patients with extensive nail involvement resulting in severe pain/limits to ambulation)

- Patient has a documented failure with or contraindication to BOTH oral therapies, terbinafine AND itraconazole
- Treatment is intended as monotherapy and not to be combined with oral treatment
- Patient has experienced an inadequate response, adverse event, intolerance, or contraindication to a 48 week treatment course of the generically available ciclopirox, despite good adherence

Approval will be for **48 weeks**. (Only 1 approval allowed in a lifetime. Continuation not approvable.)

II. The aforementioned drugs are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Brand Name	Generic Name	Quantity Limit
Jublia	efinaconazole topical solution, 10%	4 mL per 30 days
Kerydin	tavaborole topical solution, 5%	N/A

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable.

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POLICY HISTORY

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