# Julia 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 Julia 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 Julia or Kerydin for the treatment of onychomycosis..

**Julia** (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. ***Julia*** 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, 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.

## REFERENCES


- De Berker D. Fungal nail disease. N Engl J Med 2009; 360:2108-2116.
- Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. British Journal of Dermatology. 2003; 148: 402-410
- Gupta AK, Drummond-Main C, Cooper EA, et al. Systematic review of nondermatophyte mold onychomycosis: diagnosis, clinical types, epidemiology and treatment. J Am Acad Dermatol 2012; 66: 494:502.
- Gupta AK, et al. Prevalence and Epidemiology of toenail onychomycosis in diabetic subjects: a multicentre survey. Br J Dermatology. 1998; 139:665-671.
- Elewski BE. Large-scale epidemiological study of the causal agents of onychomycosis: mycological findings from the multicenter onychomycosis study of terbinafine. Arch Dermatology. 1997; 133:1317-1318.
- Jaffe, R. Onychomycosis: recognition, diagnosis, and management. Arch Fam Med. 1998; 7:587-592.
- Rodgers P, Bassler M MD. Treating Onychomycosis. Am Fam Physician. 2001; 63: 663-72, 677-8.
- Scher RK. Onychomycosis: a significant medical disorder. J Am Acad Dermatol. 1996; 35(3 pt 2): S2-5.
- Goldenstein AO, Goldenstein BG. Onychomycosis. In: *UpToDate*, Rose BD (Ed.), UpToDate. Waltham, MA, 2012.
- Jublia [prescribing information]. Valeant Pharmaceuticals. Bridgewater, NJ. September 2016.

- Kerydin [prescribing information]. Anacor Pharmaceuticals, Inc. Palo Alto, CA. August 2018.
- De Berker D. Fungal nail disease. N Engl J Med 2009;360:2108-2116.
- Tosti A. Onychomycosis. Medscape [online serial]. Updated July 28, 201. Available at: http://emedicine.medscape.com/article/1105828-overview#a0156. Accessed September 17, 2014.
- Elewski BE, Rich P, Pollak R, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis: two phase III multicenter, randomized, double-blind studies. J Am Acad Dermatol. 2013;68(4):600-608.
- Westerberg DP, Voyack MJ. Onychomycosis: current trends in diagnosis and treatment. Am Fam Physician. 2013;88(11):762-770.
- Thomas J, Jacobson GA, Markowicz CK, Peterson GM, Burnet H, Sharpe C. Toenail onychomycosis: an important global disease burden. J Clin Pharm Ther. 2010;35(5):497-519.
- Crawford F, Young P, Godfrey C, et al. Oral treatments for toenail onychomycosis. A systematic review. Arch Dermatol 2002;138:811-816.
- Gupta AK, Ryder JE, Johnson AM. Cumulative meta-analysis of systemic antifungal agents for the treatment of onychomycosis. Br J Dermatol. 2004;150(3):537-544.


## POLICY HISTORY

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