

Commercial/Healthcare Exchange PA Criteria Effective: September 2015

Prior Authorization: Kerydin

Products Affected: Kerydin (tavaborole) topical solution

Medication Description:

Kerydin (tavaborole) is an oxaborole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton Rubrum* or *Trichophyton mentagrophytes*. The mechanism of action of tavaborole is to inhibit fungal protein synthesis by inhibition of an aminoacyl-transfer ribonucleic acid (tRNA) synthetase (AARS).

Covered Uses: Onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Exclusion Criteria: N/A

Required Medical Information:

1. Laboratory and chart note documentation of Onychomycosis of the toenails due to ONE of the following:
 - a. *Trichophyton rubrum*
 - b. *Trichophyton mentagrophytes*

Age Restrictions: 6 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 48 weeks

Other Criteria:

- A. Patient is at least 6 years of age or older; **AND**
- B. Patient has a confirmed diagnosis of onychomycosis of the toenails due to *Trichophyton rubrum* OR *Trichophyton mentagrophytes*.

Approve Jublia if the patient meets the following criteria (A **and** B):

- A. Patient has a diagnosis of onychomycosis with **ONE** of the following comorbidities:
 - a. Diabetes; **OR**
 - b. HIV; **OR**
 - c. Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications); **OR**
 - d. Peripheral vascular disease; **OR**
 - e. Pain caused by the onychomycosis; **AND**
- B. History of failure, contraindication, or intolerance to the following antifungal agents:
 - a. Generic oral terbinafine – AT LEAST a 3-month course of treatment; **AND**
 - b. Generic ciclopirox 8% topical solution

References:

1. Kerydin [product insert]. Anacor pharmaceuticals, Inc. Palo Alto, CA. March 2015.
2. Kerydin. Lexicomp Online [Internet database], Hudson, Ohio: Wolters Kluwer Health, Inc; March 10, 2016.
3. Product Information: KERYDIN(R) topical solution, tavaborole topical solution. Pfizer Labs (per FDA), New York, NY, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/2015
2	Update	Moved to updated template CCI Revision History:9/15, 8/16, 8/17, 7/18	All	2/14/2020