

Commercial/Healthcare Exchange PA Criteria
Effective: September 2015

Prior Authorization: Kerydin

Products Affected: Kerydin (tavaborole) topical solution, tavaborole topical 5% 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*; **AND**
- C. History of failure, contraindication, or intolerance to the following antifungal agents:
 - a. oral terbinafine (Lamisil); **AND**
 - b. ciclopirox (Penlac) topical solution

References:

1. Kerydin [product insert]. Anacor pharmaceuticals, Inc. Palo Alto, CA. March 2015.
2. Tavaborole topical solution, [product insert]. Encube Ethicals Private Limited. Plot No. C1, Madkaim Ind. Estate, Madkaim, Post: Mardol, Ponda, Goa – 403 404. INDIA. October 2020.
3. Kerydin. Lexicomp Online [Internet database], Hudson, Ohio: Wolters Kluwer Health, Inc; March 10, 2016.
4. 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

3	Update	<p>Added tavaborole topical 5% solution to products affected</p> <p>Removed the following from other criteria: Approve Jublia if the patient meets the following criteria (A and B):</p> <ul style="list-style-type: none"> A. Patient has a diagnosis of onychomycosis with ONE of the following comorbidities: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> a. Generic oral terbinafine – AT LEAST a 3-month course of treatment; AND b. Generic ciclopirox 8% topical solution D. Added the following to other criteria: History of failure, contraindication, or intolerance to the following antifungal agents: <ul style="list-style-type: none"> a. oral terbinafine (Lamisil); AND b. ciclopirox (Penlac) topical solution 	<p>Products Affected</p> <p>Other criteria</p>	1/1/2021
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