Clinical Policy: Tavaborole (Kerydin)

Reference Number: PA.CP.PMN.105
Effective Date: 03.01.18
Last Review Date: 01.19 Revision Log

Description
Tavaborole (Kerydin®) is an oxaborole antifungal.

FDA Approved Indication(s)
Kerydin is indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness that Kerydin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Onychomycosis (must meet all)**:**

1. Diagnosis of onychomycosis of the toenails;
2. Age ≥ 6 years;
3. Failure of a 12-week trial of oral terbinafine at up to maximally indicated doses within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 10 ml (1 bottle) per claim.

Approval duration: 48 weeks

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Onychomycosis (must meet all)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.
3. If request is for a dose increase, new dose does not exceed 10 mL (1 bottle) per claim.

Approval duration: 48 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 48 weeks (whichever is less); or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized):

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
terbinafine (Lamisil®)	Toenail onychomycosis: 250 mg PO once daily for 12 weeks	250 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Onychomycosis	Apply to affected toenails once daily for 48 weeks	Once daily

VI. Product Availability

Solution (4 mL and 10 mL bottles): 5%

VII. References

1. Kerydin Prescribing Information. New York, NY: Pfizer, Inc.; August 2018. Available at: https://www.kerydin.com/. Accessed September 27, 2018.
2. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-70.
3. Lamisil Tablets Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed September 27, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
	11.03.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: added quantity limit per claim; updated age requirement from ≥ 18 years to ≥ 6 years per PI; references reviewed and updated.	01.19	