Clinical Policy Title:	tavaborole
Policy Number:	RxA.187
Drug(s) Applied:	Kerydin®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Tavaborole (Kerydin®) is an oxaborole antifungal. It is indicated for the topical treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tavaborole (Kerydin®)	Onychomycosis	Apply to affected toenails once daily for 48 weeks.	Once daily

Dosage Forms

- Topical Solution, 5%

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 1 bottle per claim.

Approval Duration
Commercial: 48 weeks
Medicaid: 48 weeks

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 bottle per claim.

Approval Duration
Commercial: 48 weeks
Medicaid: 48 weeks

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
terbinafine	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

- Contraindication(s):
  - None reported.
- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Not Applicable.

References

1. Kerydin® Prescribing Information. New York, NY: Pfizer, Inc.; July 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204427s006lbl.pdf. Accessed March 31, 2021.
2. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-70.
3. Lipner SR, Scher RK. Onychomycosis: Treatment and prevention of recurrence. J Am Acad Dermatol. 2019 Apr;80(4):853-867. doi: 10.1016/j.jaad.2018.05.1260. Epub 2018 Jun 28. PMID: 29959962.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	03/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of	07/22/2020	09/14/2020

business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Dosage Forms was updated to exclude package sizes and include the word “topical”. 6. APPENDIX B: Therapeutic Alternatives was updated to remove Lamisil® because of discontinuation. 7. References were updated. 8. Initial and Continued Therapy Criteria updated to remove limitation of 10 mL per claim. New limitation to not exceed 1 bottle per claim.		
Policy was reviewed: 1. Clinical policy section standard verbiage was updated to include “The provision of provider samples…”. 2. Continued therapy criteria II.A.1. was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. Appendix B for therapeutic alternatives standard verbiage was updated to “Below are suggested therapeutic alternatives based on clinical guidance...”. 4. References were updated.	04/01/2021	06/10/2021