Clinical Policy: Tavaborole (Kerydin)

Reference Number: CP.PMN.105
Effective Date: 03.01.18
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that tavaborole and Kerydin are **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. If age ≥ 18 years, member meets one of the following (a or b):
   a. Failure of a 12-week trial of oral terbinafine at up to maximally indicated doses within the past 12 months;
   b. Member has intolerance or contraindication to oral terbinafine, and failure of ciclopirox 8% topical solution*, unless contraindicated or clinically significant adverse effects are experienced;

   ** Prior authorization may be required for ciclopirox 8% topical solution*
4. If request is for brand Kerydin, member must use generic tavaborole, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 10 mL (1 bottle) per 30 days.

Approval duration: 48 weeks

B. Other diagnoses/indications (must meet all)**:**

1. If request is for brand Kerydin, member must use generic tavaborole, unless contraindicated or clinically significant adverse effects are experienced;
2. One of the following (a or b):
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):

i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for brand Kerydin, member must use generic tavaborole, unless contraindicated or clinically significant adverse effects are experienced;
4. Member has not received more than 48 weeks of treatment with Kerydin;
5. If request is for a dose increase, new dose does not exceed 10 mL (1 bottle) per 30 days.

Approval duration: up to 48 weeks of total treatment

B. **Other diagnoses/indications** (must meet all)**:**

1. If request is for brand Kerydin, member must use generic tavaborole, unless contraindicated or clinically significant adverse effects are experienced;
2. One of the following (a or b):
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
      i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
      ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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 QD for 12 weeks	250 mg/day
ciclopirox 8% topical solution	Apply once daily (preferably at bedtime or eight hours before washing) to all affected nails with the applicator brush provided. Daily applications should be made over the previous coat and removed with alcohol every seven days. This cycle should be repeated throughout the duration of therapy. The safety and efficacy of using ciclopirox daily for > 48 weeks have not been established.	See dosing regimen

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: http://labeling.pfizer.com/ShowLabeling.aspx?id=5388. Accessed November 7, 2024.
2. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-70.
3. Gupta AK, Daigle D, and Foley KA. Network meta-analysis of onychomycosis treatments. Skin Appendage Disorder. 2015; 1: 74-81.
4. Gupta AK, Foley KA, Mays RR, Shear NH, and Piguet V. Monotherapy for toenail onychomycosis: a systematic review and network meta-analysis. British Journal of Dermatology. 2019. DOI 10.1111/bjd.18155.
5. Ameen M, Lear JT, Madan V, Mustapa MF, and Richardson M. British Association of Dermatologists' guidelines for management of onychomycosis 2014. British Journal of Dermatology. 2014; 171: 937-958.
6. Clinical Pharmacology [database online]. Elsevier. Updated periodically. Available at: https://www.clinicalkey.com/pharmacology/. Accessed November 7, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: clarified redirection applies to age 18 or older similar to Jublia; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.17.20	02.21
1Q 2022 annual review: for continued therapy added criteria to ensure member has not received more than 48 weeks of treatment; modified approval duration to allow up to 48 weeks of total treatment per prescribing information; references reviewed and updated.	09.21.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: added requirement for use of generic tavaborole for brand Kerydin requests; clarified dose limits in criteria from 1 bottle per claim to 1 bottle per 30 days; references reviewed and updated.	10.13.22	02.23
1Q 2024 annual review: no significant changes; added note that prior authorization may be required for ciclopirox 8% topical solution; references reviewed and updated.	10.24.23	02.24
1Q 2025 annual review: added tavaborole to "tavaborole and Kerydin are medically necessary when the following criteria are met" standard template language as generic requires prior authorization; for Appendix B, removed brand Penlac® as branded product is obsolete; references reviewed and updated.	11.06.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.