Clinical Policy: Tavaborole (Kerydin)
Reference Number: CP.PMN.105
Effective Date: 03.01.18
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

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 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. 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;
      4. Dose does not exceed 10 mL (1 bottle) per claim.
   Approval duration: 48 weeks

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. Onychomycosis (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy.
   
   Approval duration: Duration of request or 48 weeks (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>terbinafine (Lamisil®)</td>
<td>Toenail onychomycosis: 250 mg PO once daily for 12 weeks</td>
<td>250 mg/day</td>
</tr>
<tr>
<td>ciclopirox 8% topical solution (Penlac®)</td>
<td>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 &gt; 48 weeks have not been established.</td>
<td>See dosing regimen</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onychomycosis</td>
<td>Apply to affected toenails once daily for 48 weeks</td>
<td>Once daily</td>
</tr>
</tbody>
</table>

VI. Product Availability

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

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New policy created</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Policy split from CP.CPA.54 Efinaconazole (Jublia), Tavaborole (Kerydin) for Centene commercial line of business-retired.</td>
<td></td>
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<tr>
<td>- New policy for Medicaid line of business.</td>
<td></td>
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<tr>
<td>- Age added per safety guidance endorsed by Centene Medical Affairs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Specified duration of trial of oral terbinafine for toenail onychomycosis per PI and a timeframe of within the past 12 months</td>
<td>11.03.17</td>
<td>02.18</td>
</tr>
<tr>
<td>- References reviewed and updated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1Q 2019 annual review: added quantity limit per claim; updated age requirement from ≥ 18 years to ≥ 6 years per PI; references reviewed and updated.</td>
<td>09.27.18</td>
<td>02.19</td>
</tr>
</tbody>
</table>
Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1Q 2020 annual review: added HIM line of business, retired HIM.PA.117; added (for Commercial/Medicaid)/modified (for HIM) requirement for ciclopirox 8% topical solution failure if member has intolerance or contraindication to oral terbinafine; references reviewed and updated.</td>
<td>10.28.19 02.20</td>
</tr>
</tbody>
</table>

**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.

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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.

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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.

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