ONYCHOMYCOSIS

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onmel</td>
<td>itraconazole</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Jublia</td>
<td>efinaconazole</td>
<td>48 weeks</td>
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<tr>
<td>Kerydin</td>
<td>tavaborole</td>
<td>48 weeks</td>
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Approvable Criteria:

1. Is the member’s diagnosis onychomycosis (tinea unguium) of the toenail confirmed by potassium hydroxide (KOH) microscopy or fungal culture (Trichophyton rubrum or Trichophyton mentagrophytes)?
   - If yes, continue to #2.
   - If no, do not approve.
2. Does the member have Large Group benefits (Plan Codes beginning with KL, KF, IL)?
   - If yes, continue to #3.
   - If no, do not approve. (Benefit Exclusion)
3. Does the member have the following concomitant conditions?
   a. Pain surrounding the nail with soft tissue involvement; OR
   b. A diagnosis of diabetes mellitus; OR
   c. A diagnosis of peripheral vascular disease; OR
   d. A diagnosis of immunosuppression.
      - If yes, continue to #4 for Onmel or #5 for Jublia and Kerydin.
      - If no, do not approve.
4. Has the member tried and failed a generic oral antifungal (e.g., itraconazole, terbinafine)?
   - If yes, approve for 12 weeks.
   - If no, do not approve.
5. Has the member tried and failed a generic oral antifungal (e.g., itraconazole, terbinafine) AND generic ciclopirox 8%?
   - If yes, approve for 48 weeks.
   - If no, do not approve.

Dosage and Administration:

**Onmel:** 200mg PO once daily for 12 weeks.

**Jublia and Kerydin:** Topically once daily for 48 weeks.

**ONMEL QL = 30 x 30 days; Max of 90 days**

* References: