MEDICATION POLICY

Generic Name: Terbinafine

Therapeutic Class or Brand Name: Lamisil®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Terbinafine tablets (generic)

Non-Preferred: Lamisil® tablets

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 10/8/16

GPI Code: 1100008010

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of Onychomycosis.

II. Minimum age requirement: 18 years old.

III. Non-preferred products (i.e. Lamisil ® tablets) require a documented clinical reason containing details as to why generic terbinafine is not appropriate or is contraindicated.

Exclusion Criteria:

- Chronic or active liver disease.

Other Criteria:

- The optimal clinical effect from treatment with Lamisil® is not seen immediately after treatment is completed, but is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail.

Quantity/Days Supply Restrictions:

- Quantities of up to 30 tablets per 30 days.

Approval Length:

- **Authorization:**
  - Fingernail onychomycosis: 6 weeks per 52 week period.
  - Toenail onychomycosis: 12 weeks per 52 week periods.

- **Re-Authorization:** N/A

Appendix:

N/A

References:

1. NPS.
2. http://www.pharma.us.novartis.com/product/pi/pdf/Lamisil_tablets.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
10/8/2016	1. **Changed** "N/A" **to** "Preferred: Terbinafine tablets (generic); Non-Preferred: Lamisil® tablets" **following Applicable Drugs**. 2. **Changed** "III. Brand name Lamisil® requires a documented trial and failure of or contraindication to generic Terbinafine" **to** "III. Non-preferred products (i.e. Lamisil ® tablets) require a documented clinical reason containing details as to why generic terbinafine is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 3. **Changed** "N/A" **to** "Chronic or active liver disease" **under Exclusion Criteria**. 4. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Lamisil.pdf" **from References** (link no longer valid).
5/22/2015	1. **Changed** "N/A" **to** "The optimal clinical effect from treatment with Lamisil® is not seen immediately after treatment is completed, but is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail" **under Other Criteria**. 2. **Changed** "May be authorized for up to a total of 16 weeks in a 52 week period" **to** "Fingernail onychomycosis: 6 weeks per 52 week period; Toenail onychomycosis: 12 weeks per 52 week period" **for Authorization under Approval Length**. 3. **Changed** "Same process as initial PA" **to** "N/A" **for Re-Authorization under Approval Length**. 4. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Lamisil.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Lamisil.pdf" **under References**.
1/7/2014	1. **Adapted policy to new format.** 2. **Added** "Minimum age requirement: 18 years old" **to Prior Authorization Criteria**. 3. **Changed Quantity/Days Supply Restrictions from** "30 tablets per 30 days" **to** "Quantities of up to 30 tablets per 30 days". 4. **Changed Authorization under Approval Length from** "Authorized for 16 weeks per calendar year" **to** "May be authorized for up to a total of 16 weeks in a 52 week period". 5. **Updated references** to include package insert.