

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Onychomycosis Policy

Drug(s): LAMISIL (terbinafine), PENLAC (ciclopirox sol 8%), SPORANOX (itraconazole)

Covered Uses: Treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium). Lamisil Oral Granules is indicated for the treatment of tinea capitis in patients 4 years of age and older. Itraconazole is indicated for Blastomycosis, Histoplasmosis, Aspergillosis in patients who are intolerant of or who are refractory to amphotericin B therapy. Topical ciclopirox is indicated for onychomycosis due to trichophyton rubrum. All criteria in "other criteria" section must be met for coverage.

Required Medical Information: Chart notes indicating medical history and immunocompetence status, KOH result or culture, changes in activities of daily living (ADLs). For itraconazole use in lung fungal infections: fungal cultures and other relevant laboratory studies, date of transplant, start date of itraconazole.

Age Restrictions: Terbinafine granules not covered under 4 years or over 12 years of age. Terbinafine tablets are not covered for less than 18 years old, Ciclopirox 8% not covered for less than 12 years old.

Prescriber Restrictions: N/A

Other Criteria: The use of terbinafine or itraconazole may be medically necessary if the following criteria are met:

- Member is immunocompromised (e.g. HIV/AIDS, undergoing chemotherapy, transplant recipient) or has a history of peripheral vascular disease (e.g. diabetes), **and/or**
- ADLs are significantly compromised due to the infection **and**
- has a positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with a dermatophyte or Candida infection.

The use of ciclopirox 8% may be medically necessary if the following criteria are met:

- member has a contraindication or significant drug interaction to/with terbinafine and itraconazole.

Onychomycosis dosing and duration

Terbinafine for Fingernail infections: 250mg daily for 6 weeks.

Toenail infections: 250mg daily for 12 weeks.

Itraconazole for Fingernail infections: 200mg daily for 8 weeks or 200mg twice daily x 1 week/month for 2 courses,

Toenail infections: 200mg daily for 12 weeks.

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Members who have a significant tinea pedis infection and do not meet the criteria for treatment of onychomycosis may qualify for up to a 14-day course of terbinafine treatment if they have failed at least two (2) topical antifungal treatment courses (4 to 6 weeks duration).

The use of itraconazole for fungal infections may be medically necessary for the following:

1. Blastomycosis, pulmonary and extrapulmonary.
2. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis.
3. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Exclusion Criteria:

- Combination therapy with more than one agent (terbinafine, itraconazole, ciclopirox) will not be covered.
- Itraconazole will not be covered if there is no documented terbinafine failure, lack of indication, or other contraindications to terbinafine use.
- Ciclopirox will not be covered if no documentation of a contraindication or significant drug interaction to/with terbinafine and itraconazole.
- Terbinafine for Fingernail infections will not be covered for greater than 250mg daily and 6 weeks per 365 days.
- Terbinafine for Toenail infections will not be covered for greater than 250mg daily for 12 weeks per 365 days.
- Itraconazole for fingernail infections is not covered if greater than 200mg daily for 8 weeks or 200mg twice daily x 1 week/month for 2 courses per 365 days.
- Itraconazole for toenail infections not covered for greater than 200mg daily for 12 weeks per 365 days.
- Lamisil Oral Granules are not covered for more than one packet daily for 6 weeks per 365 days.
- Itraconazole for Blastomycosis, Histoplasmosis, Aspergillosis is not covered for greater than 12 months of therapy.

Coverage Duration:

As stated above