VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

LAMISIL (terbinafine hydrochloride tablets): ANTI-FUNGAL

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Description

Terbinafine tablet is an allylamine antifungal agent indicated for the treatment of onychomycosis of the toenail or fingernail caused by dermatophytes (tinea unguium).[1, 67] Other uses of terbinfine tablets besides onychomycosis are discussed in this policy. This policy does not include terbinafine oral granules, which are indicated for the treatment of tinea capitis in children aged 4 years and older.[64] For more information on the safety and efficacy of terbinafine in the treatment of onychomycosis, please refer to the *Antifungal Therapy for Onychomycosis Therapeutic Guideline*.

Recommended Authorization Criteria

Coverage of terbinafine tablets are recommended for those who meet one of the following criteria:

FDA-Approved Indications

1. **Onychomycosis (refer to the *Antifungal Therapy for Onychomycosis Therapeutic Guideline* for the criteria).** Terbinafine is FDA-approved for the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium).[1,67]

Other Uses with Supportive Evidence

2. **Tinea corporis.** Approve after a trial of a topical antifungal agent, except for extensive conditions. Terbinafine has been useful for this condition,[2-5] however, many topical antifungal agents are equally effective and are indicated for tinea corporis.[12-14] However, for extensive conditions, oral antifungal agents may be needed or preferred for practical reasons.

3. **Tinea cruris, faciei, manuum, pedis, and imbricate.** Approve after a trial of a topical antifungal agent. Terbinafine has been useful for these various tinea conditions;[2-3,5-11,15-16] however, many topical antifungal agents are similarly effective and some are indicated for these conditions.[12-14,17]

4. **Plantar- or moccasin-type dry tinea pedis.** Approve. Oral antifungal therapy is often required for plantar or moccasin-type tinea pedis as topical antifungal agents have led to poor responses or frequent relapses. Studies with terbinafine have shown good results in the treatment of plantar/moccasin-type tinea pedis. [10,18-22]

5. **Black piedra.** Approve. Case reports document that terbinafine has been useful in black piedra, a condition with limited pharmacologic options.[23-25]

6. **Tinea capitis.** Approve. Terbinafine tablets have been effective in the treatment of tinea capitis,[29-40]

7. **Tinea barbae.** Approve. Case reports have described terbinafine as useful in tinea barbae.[42-43]

8. **Cutaneous (skin) candidiasis.** Approve after a trial of a topical antifungal agent and an oral azole antifungal (eg, ketoconazole, fluconazole, or itraconazole). Terbinafine led to a mycological cure rate of 82% of patients with skin candidiasis in a 4-week randomized, double-blind, multicenter study involving 118 patients.[44] Topical antifungals agents and other azole antifungals are also effective for this condition.

9. **Other superficial fungal skin infections.** Approve after a trial of a topical antifungal agent or an oral antifungal agent (eg, itraconazole, fluconazole). Terbinafine has been used in various superficial fungal infections (eg, seborrheic dermatitis,[45] cutanenous leishmaniasis,[46-47] cutaneous alternariosis,[48] and other subcutaneous infections[49] and cutaneous sporotrichosis[50-51,65], chromoblastomycosis[66]). Other antifungal agents and topical antifungal agents have been reported to be efficacious in some of these conditions, such as seborrheic dermatitis.[52]

10. **Eumycetoma/mycetoma.** Approve. In a single-center, open-label study[61] 27 patients with eumycetoma received terbinafine 500 mg BID for 24-48 weeks. An improvement or cure was noted in approximately 80% of patients. This subcutaneous mycoses is difficult to treat and usually involves surgical intervention.

Exclusions

Coverage of terbinafine tablets is *not* recommended in the following circumstances:

1. **Tinea versicolor (pityriasis versicolor).** Oral terbinafine is not recommended for the treatment of tinea versicolor.[53-54] Although topical terbinafine is effective for tinea versicolor, oral treatment is not effective.

2. **Systemic fungal infections.** Data for terbinafine is confined to case serious or case reports such as compassionate cases of bronchopulmonary *aspergillosis*[55], relapsing *aspergillus* bronchitis[56] and *Curvularia lunata* endocarditis[57] and others[58]. Very little data exist on the use of terbinafine in the treatment of systemic fungal infections,

therefore, its use for these indications should be considered investigational at this time.

3. **Oral or esophageal candidiasis.** Oral terbinafine is not recommended for the treatment of oral or esophageal candidiasis. Limited data are available regarding the use of terbinafine for these infections.[59-60]

4. **Vaginal candidiasis.** Oral terbinafine is not recommended for the treatment of vaginal candidiasis. Limited data have studied its efficacy for this condition and the 2006 Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases (STD) guidelines regarding vaginal candidiasis recommended azole antifungals (e.g., fluconazole) for this condition.[62-63]

5. Coverage is not recommended for circumstances not listed in *Recommended Authorization Criteria*.

	Lamisil
A. Onychomycosis 1. One of the following: • Member has diabetes **OR**, • Member has an iatrogenically-induced or disease-associated immunosuppression, such as that due to AIDS, antirejection treatment for bone marrow or solid organ transplant, or chemotherapy for cancer **OR**, • Member has a systemic dermatosis with impaired skin integrity (e.g., pemphigus, ichthyosis) **OR**, • Member has a significant vascular compromise (peripheral)	X
For onychomycosis, new courses of therapy should not be initiated until 32 weeks following the end of therapy unless infection is noted in a previously unaffected nail (since cure rate continues to increase through the 11th month following initiation of a 12 week course of therapy).	

References

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