

Antifungal Agents for Onychomycosis *Lamisil*[®], *Terbinex*[®] and *Sporanox*[®]

To Initiate a Coverage Review, call 1 800 753-2851

Covered Medications
<ul style="list-style-type: none"> ➤ Terbinafine (<i>Lamisil</i>[®]), terbinafine with hydroxy chitosan solution (<i>Terbinex</i>[®]) and itraconazole (<i>Sporanox</i>[®] and generic)

What They Do and How They're Used
<ul style="list-style-type: none"> ➤ Onychomycosis is a localized infection of the nail or nail bed characterized by thickened, brittle, yellow nails. Onychomycosis is often treated to avoid irritation, swelling, pain and discomfort. In severe cases, the infection can lead to disfigurement and loss of mobility. If the fungal infection remains untreated, the affected nails can act as a reservoir for other infection (e.g., bacterial infection). ➤ Dermatophytes (fungal parasites) cause 90% of all cases. Yeast (<i>Candida</i> species) cause 7% of infections and nondermatophyte molds 3% of infections. These nondermatophyte infections are difficult to eradicate using antifungal agents. ➤ Antifungal agents exhibit the "reservoir effect," whereby therapeutic concentrations of the medications remain in the nail plate for several months after therapy has stopped. Following the completion of a course of antifungal therapy, the nail may still appear abnormal until healthy nail tissue begins to appear. Toenail onychomycosis requires a longer treatment regimen than fingernail onychomycosis because of inherent slower growth of toenails.

Rationale for Coverage Authorization
<ul style="list-style-type: none"> ➤ To provide coverage for the treatment of diagnostically confirmed onychomycosis where the patient has diabetes mellitus, peripheral vascular disease, swelling and/or redness in the surrounding nail tissue or pain in affected nail(s), and for immunocompromised patients. ➤ To provide coverage for treatment of Intertrigo infection (body fold area) or vulvo-vaginal candidiasis when the patient has failed or is unable to receive treatment with topical therapy and fluconazole (<i>Diflucan</i>[®]) ➤ To provide coverage for treatment of tinea infections not responsive to topical therapy <p><u>Please note:</u> <i>Terbinex</i> will only be approved for the diagnosis of diagnostically confirmed onychomycosis where the patient has diabetes mellitus, peripheral vascular disease, swelling and/or redness in the surrounding nail tissue or pain in affected nail(s), and for immunocompromised patients.</p>

Benefit Design
Coverage is determined through prior authorization of every claim.

Coverage Authorization Criteria
Benefit coverage is provided for 6 months for the treatment of onychomycosis; 3 months for tinea infections; and as prescribed for other listed fungal infections. (As noted previously, <i>Terbinex</i> can only be approved for the treatment of onychomycosis.)

References
Alexander BD, Perfect JR. Antifungal resistance trends towards the year 2000. <i>Drugs</i> . 1997;54:657-678.
Chiritescu MM, Chiritescu ME, Scher RK. Newer systemic antifungal drugs for the treatment of onychomycosis. <i>Clinics in Podiatric Medicine and Surgery</i> . 1996;13:741-759.
Debruyne D, Coquerel A. Pharmacokinetics of Antifungal Agents in Onychomycoses. <i>Clin Pharmacokinet</i> . 2001; 40 (6): 441-472.
Gilbert D, Moellering RC, Sande MA. (eds): <i>The Sanford Guide to Antimicrobial Therapy</i> , 28th ed. Vienna, VA, Antimicrobial Therapy, Inc. 1998, p74.

Gupta AK, Sauder DN, Shear NH. Antifungal agents:an overview. part II. *J Am Acad Dermatol.* 1994;30:911-933.

Hospenthal D, Bennett JE. A review of current therapy for superficial and deep fungal infections. *Contemp Int Med.* 1998;10:42-52.

Product Information: Fluconazole tablets (*Diflucan*[®] - Pfizer) 2003.

Product Information: Itraconazole tablets (*Sporanox*[®] - Janssen) 2004.

Product Information: Terbinafine tablets (*Lamisil*[®] - Novartis) 2004.

Trepanier E, Amsden GW. Current issues in onychomycosis. *Ann of Pharmacother.* 1998;32:204-214.