



CIGNA PHARMACY COVERAGE POLICY

This Coverage Policy should NOT be used for Great-West benefit plans.

Subject Oral Onychomycosis Antifungal Therapy: [Terbinafine (Lamisil®), Itraconazole (Sporanox®)]

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Hyperlink to Related Coverage Positions

Ciclopirox (Penlac® Nail Lacquer)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA

Coverage Policy

CIGNA covers oral antifungal therapy [terbinafine (Lamisil®), itraconazole (Sporanox®)] for the treatment of onychomycosis in diabetic or immunocompromised individuals.

In individuals who are not diabetic or immunocompromised, CIGNA covers oral antifungal therapy [terbinafine (Lamisil®), itraconazole (Sporanox®)] as medically necessary for treatment of onychomycosis when the following criteria are met:

- diagnosis of fungal infection confirmed by either a positive potassium hydroxide (KOH) stain, para-aminosalicylic acid (PAS) stain, positive dermatophyte testing medium (DTM) or positive fungal culture
- oral anti-fungal therapy for onychomycosis has not been used within the previous 32 weeks
- **EITHER** of the following:
 - patient experiences pain, limiting normal activity
 - patient has significant peripheral vascular compromise

Note: Coverage approval will extend to 12 weeks of therapy for toenail onychomycosis and six weeks for fingernail onychomycosis. CIGNA allows PULSE DOSING with itraconazole (Sporanox®) ONLY. There is a maximum of TWO pulses for fingernails and THREE pulses for toenails.

FDA Approved Indications

Lamisil Tablets

Lamisil tablets are indicated for the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium). Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.

Sporanox

Sporanox (itraconazole) capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients: blastomycosis, pulmonary and extrapulmonary histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; and aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. Specimens for fungal cultures and other relevant laboratory studies (wet mount, histopathology, serology) should be obtained before therapy to isolate and identify causative organisms. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly.

Sporanox capsules are also indicated for the treatment of the following fungal infections in non-immunocompromised patients: onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium); and onychomycosis of the fingernail due to dermatophytes (tinea unguium). Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.

FDA Recommended Dosing

Lamisil Tablets

Lamisil (terbinafine hydrochloride tablets) tablets, one 250 mg tablet, should be taken once daily for 6 weeks by patients with fingernail onychomycosis. Lamisil, one 250 mg tablet, should be taken once daily for 12 weeks by patients with toenail onychomycosis. The optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail.

Sporanox

Treatment of Blastomycosis and Histoplasmosis

The recommended dose is 200 mg once daily (2 capsules). If there is no obvious improvement, or there is evidence of progressive fungal disease, the dose should be increased in 100-mg increments to a maximum of 400 mg daily. Doses above 200 mg/day should be given in two divided doses.

Treatment of Aspergillosis

A daily dose of 200 to 400 mg is recommended.

Treatment in Life-Threatening Situations

In life-threatening situations, a loading dose should be used whether given as oral capsules or intravenously. Capsules: although clinical studies did not provide for a loading dose, it is recommended, based on pharmacokinetic data, that a loading dose of 200 mg (2 capsules) three times daily (600 mg/day) be given for the first 3 days of treatment. Treatment should be continued for a minimum of three months and until clinical parameters and laboratory tests indicate that the active fungal infection has subsided. An inadequate period of treatment may lead to recurrence of active infection.

Treatment of Onychomycosis

Toenails with or without fingernail involvement: The recommended dose is 200 mg (2 capsules) once daily for 12 consecutive weeks. Fingernails only - the recommended dosing regimen is 2 treatment pulses, each consisting of 200 mg (2 capsules) b.i.d. (400 mg/day) for 1 week.

Black Box Warning

Congestive Heart Failure: Sporanox (itraconazole) capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration, discontinue administration. Drug Interactions: Coadministration of cisapride, pimozide, quinidine,

dofetilide, or levacetylmethadol (levomethadyl) with Sporanox capsules is contraindicated. Sporanox, a potent cytochrome P450 3A4 isoenzyme system (CYP3A4) inhibitor, may increase plasma concentrations of drugs metabolized by this pathway. Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death have occurred in patients using cisapride, pimozide, levacetylmethadol (levomethadyl), or quinidine, concomitantly with Sporanox and/or other CYP3A4 inhibitors.

Drug Availability

Lamisil Tablets

Lamisil tablets are supplied as white to yellow-tinged white circular, bi-convex, bevelled tablets containing 250 mg of terbinafine imprinted with "LAMISIL" in circular form on one side and code "250" on the other.

Sporanox

Sporanox capsules are available containing 100 mg of itraconazole, with a blue opaque cap and pink transparent body, imprinted with "JANSSEN" and "SPORANOX 100." The capsules are supplied in unit-dose blister packs of 3 x 10 capsules, bottles of 30 capsules, and in the PulsePakR containing 7 blister packs x 4 capsules each.

General Background

Pharmacology

Onychomycosis is an infection of the fingernails and toenails caused by dermatophytes, yeast, and molds. Both itraconazole and terbinafine are FDA-labeled for onychomycosis. The mechanism of action of these agents has not been fully determined. Terbinafine is considered fungicidal, and itraconazole is considered fungistatic. They inhibit the production of ergosterol, a vital component of fungal cell-wall synthesis, although the mechanism by which they do so differs between the classes.

Itraconazole has the longest half-life and can be administered as pulse dosing, characterized by one week of daily dosing followed by three weeks of no drug. Terbinafine is given daily for 6–12 weeks. Terbinafine and itraconazole are extensively bound to plasma proteins. Due to terbinafine's lipophilicity, the terminal half-life of terbinafine from skin and adipose tissue is 200–400 hours. Terbinafine and itraconazole are retained in the nail tissue for up to ten months and six to nine months, respectively, after ingestions. Terbinafine concentrations found in the nail are around 100-fold higher than the minimum inhibitory concentration (MIC) of the drug against dermatophytes.

Guidelines

The American Academy of Dermatology guidelines for the diagnosis and treatment of onychomycosis recommends the agents appropriate for dermatophyte onychomycosis include fluconazole, griseofulvin, itraconazole, ketoconazole and terbinafine. Both griseofulvin and ketoconazole have fallen out of favor due to a lack of efficacy, significant drug interactions, and side effects. Terbinafine is the only "cidal" antifungal and has the best efficacy profile.

The Infectious Diseases Society of America (IDSA) recommends that for onychomycosis in general, griseofulvin should not be used, and that newer antifungals, including terbinafine and itraconazole, offer a more effective alternative. With respect to *Candida* onychomycosis, the IDSA states that terbinafine has very limited activity and that therapy with itraconazole appears to be effective.

Clinical Efficacy

Several studies published in the literature compared itraconazole to terbinafine. These studies are discussed according to type of onychomycosis, compared agents and type of regimen (continuous or intermittent therapy). Continuous therapy is a drug regimen that is scheduled as regular daily doses given throughout the course of therapy. Intermittent, or pulse therapy, is a drug regimen that is characterized by periods of regular dosing followed by drug-free intervals, or a drug regimen that is dosed once-weekly.

Dermatophyte Onychomycosis: Terbinafine vs. Itraconazole

- **Continuous Therapy**

Five published studies compare continuous regimens of terbinafine to itraconazole in dermatophyte infections. Follow-up times in these studies ranged from six months to three years following discontinuation of treatment. All these studies used doses and treatment duration recommended by the manufacturer: itraconazole 200 mg daily for 12 weeks or terbinafine 250 mg daily for 12 weeks. Diagnosis was confirmed by potassium hydroxide (KOH) microscopy and culture. Four of the studies were double-blind, randomized, placebo-controlled trials. In each study, both active treatments were significantly better than placebo. However, there was no consensus as to whether itraconazole or terbinafine was a superior antifungal agent. The Arenas and the Degreef studies did not find significant differences between the two treatment arms. However, the Brautigam (1998), the DeBacker (1998), and the DeCuyper (1999) studies found significant differences in several primary outcomes, especially mycological cure rate. Brautigam and DeBacker both conducted studies which were sponsored by the manufacturer of terbinafine, and both found it was significantly superior to itraconazole in mycological cure rate: Brautigam at one year, and DeBacker at nine months. They also found that terbinafine was superior to itraconazole in percent with a negative culture at the same time-points. DeBacker et al. found significant results in percent with negative microscopy at the nine-month follow-up.

The differences in findings between these studies were not attributable to study size. Degreef et al. (1999), who found no difference, conducted a large study of 292 patients. However, they only followed patients up to six months after treatment was discontinued. The studies that found a significant difference followed patients for nine months or more. When observation is discontinued early, relapses may be missed, and benefits may be underestimated if the agents provide long-term benefits. Terbinafine is a fungicidal agent and, consequently, patients are likely to continue to have improvement long after concentrations in the nail fall below therapeutic levels. DeCuyper et al., who found itraconazole to be superior at nine months, reported that itraconazole-treated patients were more likely to relapse at two years following treatment; however, they did not report statistical values for this finding.

- **Intermittent Therapy**

Three studies compared continuous terbinafine to various pulse regimens, and one study compared a course of pulse terbinafine to pulse terbinafine followed sequentially by itraconazole. Outcomes were assessed at weeks 16, 48, and 72.

Evans et al. (1999) was the only randomized, double-blind, placebo-controlled trial among these studies. It compared continuous terbinafine for 12 and 16 weeks to pulse itraconazole for the same time periods. The authors reported that both arms of terbinafine treatment were superior to itraconazole for all endpoints at week 72 (one year after treatment was discontinued), and that rates of clinical cure for terbinafine improved clearly and consistently until that point. No significant improvement was found with itraconazole beyond week 48.

Tosti et al. (2000) performed two open-label studies. The first compared regimens of pulse terbinafine, pulse itraconazole, and continuous terbinafine, and only followed patients up to six months after discontinuation of treatment. They found that 94% of continuous terbinafine patients and 80% of pulse terbinafine patients achieved mycological cure, compared to only 75% of pulse itraconazole patients. The authors did not report statistical data for this finding, although they did report statistically significant results for other endpoints. The second Tosti study was a follow-up to the first, in which patients who achieved mycological cure were monitored for relapse rate. A higher percentage of patients treated with itraconazole relapsed, but there was no statistical significance. This was a small study, however, and power was not sufficient to detect a difference.

Gupta et al. (2001) compared pulse terbinafine to a combination of pulse terbinafine and itraconazole. This study found statistically significant differences in mycological cure rate at week 72; combination itraconazole/terbinafine was superior to terbinafine alone.

Overall data show that a continuous-dose regimen of terbinafine is superior to pulse-dose itraconazole in the treatment of patients with onychomycosis. Continuous-dose terbinafine may appear to be more effective than pulse-dose terbinafine. Intermittent dosing with either drug may be similar in efficacy.

Adverse Reactions

Those who suffer from the disease cite a substantial negative effect on their quality of life. Onychomycosis can give rise to complications such as cellulitis and, therefore, further compromise the limb in those with diabetes or peripheral vascular disease. While these complications may not be common, they are certainly serious. Onychomycosis can lead to much more serious consequences in patients with diabetes mellitus, such as nail removal, secondary bacterial infection, and increased risk of amputation. Fungal infection of the nails is also important in immunocompromised patients (i.e., patients diagnosed with human immunodeficiency virus (HIV), positive/acquired immunodeficiency syndrome [AIDS], cancer patients, particularly those taking anticancer medications, and transplant patients who are also taking drugs which suppress the immune system). These patients should be treated immediately to prevent future health problems.

Topical therapy is ineffective, and does not resolve distal subungual onychomycosis. Systemic therapy may require as long as six months for fingernails and 12–18 months for toenails. In extreme cases, depending on the degree of patient pain, surgical removal of the nail may be an option.

Itraconazole and terbinafine have the potential to cause serious hepatotoxicity. Fatalities have occurred with both agents, and there has been no relationship found between total daily dose, duration of therapy or age. Patients should be counseled to report any symptoms of liver dysfunction to their physician. Headache and gastrointestinal disturbances are the most commonly reported adverse reactions.

Coding/Billing Information

Note: This section is not in use.

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