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Lamisil[®]/terbinafine and Sporanox[®]/itraconazole Prior Authorization Criteria

Brand	Generic	Dosage Form
Lamisil [®]	terbinafine	oral tablets*, oral granules
Sporanox [®]	itraconazole	oral capsules*, oral solution

*generic available and included in the program

PROGRAM OBJECTIVES

The intent of the Prior Authorization (PA) Criteria for Lamisil tablets and oral granules and Sporanox capsules and oral solution is to assure appropriate selection of patients for treatment according to product labeling and/or clinical trials and/or guidelines and to discourage cosmetic utilization. The PA defines appropriate use as confirmed fungal nail infections that are considered medically necessary to treat (patient has comorbid condition such as diabetes, peripheral vascular insufficiency, immune deficiency, secondary bacterial skin condition, or pain limiting normal activity).

PROGRAM FUNCTIONALITY

Electronic Edits

The overall process for a PA will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug listed in Table 1 below, the system will reject the claim with the message indicating that PA is necessary. The Prior Authorization (PA) Criteria for Approval would then be applied to requests submitted by the patient's practitioner for evaluation.

Table 1: Targeted Agents for Lamisil and Sporanox Prior Authorization

Lamisil (terbinafine) ^a	GPI (multisource code)
250 mg tablet ^b	11000080100310 (M, N, O, Y)
granules 125 mg	11000080103020 (M, N, O, Y)
granules 187.5 mg	11000080103030 (M, N, O, Y)
Sporanox (itraconazole)	
100 mg capsule ^b	11407035000120 (M, N, O, Y)
10 mg/ml oral solution	11407035002020 (M, N, O, Y)

^a Lamisil cream and spray are not included in the program

^b generic available and included in the program

Prior Authorization (PA) Criteria for Approval

No claims for Lamisil/terbinafine or Sporanox/itraconazole will be automatically paid at the point of sale. The Prior Authorization (PA) Criteria for Approval provide the manual review process for all claims for targeted agents in this PA program.

Recommended dosing for patients with fingernail onychomycosis is Lamisil 250 mg once daily for 6 weeks.^{1,2} Toenail onychomycosis requires Lamisil 250 mg once daily for 12 weeks.^{1,2} The optimal clinical effect of Lamisil is seen some months after mycological cure and cessation of treatment due to the outgrowth of healthy nail. Although Lamisil levels in the plasma decrease rapidly after termination of therapy, levels in the nail persist for up to 36 weeks after therapy is completed.^{1,2} The PA for Lamisil will allow for one full course of treatment (6 weeks for fingernails, 12 weeks for toenails). Because Lamisil levels persist, approval will be allowed once in twelve months, or one benefit year. Lamisil granules are indicated for the treatment of tinea capitis and Lamisil has proven efficacy for the treatment of tinea pedis (athlete's foot). Lamisil has proven efficacy for the treatment of cutaneous dermatophyte infections, including tinea pedis (athlete's foot)⁴ and tinea capitis;² PA requests for these indications will be for 4 to 6 weeks, depending on the diagnosis.^{2,4}

It is recommended that treatment of onychomycosis of the toenails with Sporanox 200 mg once daily be continued for 12 consecutive weeks.³ For treatment of onychomycosis of the fingernails only, Sporanox 200 mg twice daily is given in two treatment pulses of one week duration separated by a three week interval with no Sporanox administration.³ Approval for Sporanox will be for a duration of 6 months for systemic infections (such as blastomycosis, histoplasmosis, or aspergillosis), or for treatment of immunocompromised or post-transplant patients.^{8,9} Approval for oropharyngeal or esophageal candidiasis or cutaneous infections will be for 4 weeks.

Lamisil/terbinafine, Sporanox/itraconazole

Initial and Renewal Evaluation

1. Has Lamisil/terbinafine or Sporanox/itraconazole been prescribed for the treatment of onychomycosis?
If yes, continue to 2. If no, approve as follows:
 - Lamisil or terbinafine for 6 weeks for tinea capitis
 - Lamisil or terbinafine for 4 weeks for all other indications
 - Sporanox or itraconazole for 4 weeks for oropharyngeal or esophageal candidiasis or cutaneous infections;
 - Sporanox or itraconazole for 6 months for systemic infections (including histoplasmosis, blastomycosis, aspergillosis) or infections in immunocompromised or transplant patients
2. Has the patient been approved for onychomycosis treatment with the requested agent in the past 12 months?
If yes, deny. If no, continue to 3.
3. Does the patient have a diagnosis of onychomycosis AND one of the following conditions?
 - a. Diabetes mellitus
 - b. Peripheral vascular insufficiency
 - c. Immune deficiency due to medical condition or treatment (e.g. cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant)
 - d. Pain limiting normal activity
 - e. Secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrityIf yes, continue to 4. If no, deny.
4. Has the fungal nail infection been confirmed by laboratory testing (e.g., KOH preparation, fungal culture, or nail biopsy)?
If yes, approve as follows:
 - Lamisil or terbinafine for 6 weeks for fingernail infections
 - Lamisil or terbinafine for 12 weeks for toenail infections
 - Sporanox or itraconazole for two weeks of pulse therapy if fingernail infection only (each pulse consisting of 200 mg twice daily for one week, pulses separated by a three-week interval).
 - Sporanox or itraconazole for 12 weeks for toenail infections (200 mg once daily for 12 consecutive weeks)If no, deny.

CLINICAL RATIONALE

Lamisil and Sporanox are both indicated for the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium).¹⁻³ Onychomycosis is an infection of the nail with fungi which may be dermatophytes, yeasts, or molds.⁵ Dermatophyte infection is responsible for about 90% of onychomycosis cases.⁵ Non-dermatophyte molds are responsible for about 2% of toenail infections but rarely affect the fingernails.⁴ Candida infections of the fingernails are more common than toenail infections.⁵ Lamisil oral granules are indicated for treatment of tinea capitis.² Sporanox is also indicated for the treatment of immunocompromised and non-immunocompromised patients with systemic blastomycosis, histoplasmosis, and aspergillosis.³

The PA criteria for Lamisil and Sporanox allows for the treatment of onychomycosis when treatment is not solely for cosmetic reasons. Onychomycosis typically causes no symptoms other than an undesirable appearance of the nail.^{5,6} Guidelines recommend consideration of treatment if walking is uncomfortable, abnormal looking nails are causing significant psychological distress, or if the patient has diabetes, vascular disease, or a connective tissue disorder. Treatment may be necessary if the nail infection is the source of a fungal skin infection or if the person is, or may become, severely immunocompromised.⁵

Verification of infection is required for approval. Onychomycosis can be difficult to distinguish from other causes of nail dystrophy and because of slow nail growth (six months for fingernails and twelve months for toenails) evidence of treatment failure may not be apparent for several months or more. If the diagnosis is not confirmed and improvement does not occur, it is impossible to ascertain if treatment failure has occurred or if the initial diagnosis was incorrect. Guidelines on the treatment of fungal and candidal infections of the nail recommend laboratory confirmation of the diagnosis before initiation of treatment.^{5,6} An FDA public health advisory concerning the association of congestive heart failure and hepatic adverse events with the administration of Lamisil and Sporanox recommends that healthcare providers obtain nail specimens for laboratory testing prior to prescribing the medications for onychomycosis to confirm the diagnosis.⁷

Rare cases of liver failure, some leading to death or liver transplant, have occurred in patients administered Lamisil for the treatment of onychomycosis. These cases involved patients with and without pre-existing liver disease.^{1,2} It is recommended that pretreatment levels of serum transaminase (ALT and AST) be determined for all patients prescribed Lamisil.^{1,2} The PA criteria for Lamisil does not require liver function testing as a part of the approval process. However, the approval process will include letters of approval recommending testing according to product labeling and guidelines for treatment.

FDA APPROVED INDICATIONS¹⁻³

Lamisil^{1,2}

Lamisil (terbinafine) 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.

Lamisil oral granules are indicated for the treatment of tinea capitis in patients four years of age and older.

Sporanox³

Sporanox (itraconazole) capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

1. Blastomycosis, pulmonary and extrapulmonary
2. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
3. 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:

1. Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
2. 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.

REFERENCES

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Document History

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