

Itraconazole

GPI CODING:

114070350001**	Itraconazole capsules
11407035002020	Sporanox solution
114070350003**	Onmel tablets

DESCRIPTION:

The purpose of this document is to provide approval criteria and guidelines for prior authorization of benefits (PAB) for oral antifungal agents: Lamisil, Sporonox capsules and solution. Claims submitted without obtaining prior authorization of benefits will reject on the pharmacy claim system.

APPROVAL DURATION:

12 months for onychomycosis with no comorbidity
12 months for non-onychomycosis indications
Lifetime for onychomycosis with a relevant comorbidity

Onmel specific: 4 months authorization

CRITERIA FOR ITRACONAZOLE PRODUCTS

- I. Onychomycosis for patients with no relevant comorbidity (normal immune system, and no disorder which predisposes to infection in the extremities) **AND**
 - A. Evidence of functional impairment (such as loss of one or more toenails, pain, or swelling) **AND**
 - B. A confirmed fungal infection (e.g., physical exam)**OR**
 - II. Onychomycosis for patients with a relevant comorbidity (abnormal immune system [e.g., HIV positive, on immunosuppressant drugs]) and/or disorder which predisposes to infection in the extremities [e.g., Diabetes] **AND** a confirmed fungal infection (e.g., physical exam)
- OR**
- III. Tinea infections (EXCEPT for tinea unguium) when the patient has demonstrated an inadequate response to, is intolerant to, or had a confirmed adverse event with at least one prior topical therapy including, but not limited to miconazole, tolnaftate, clotrimazole, ketoconazole, econazole, nystatin, butenafine, or terbinafine

Itraconazole capsules are covered with prior authorization for the following non-onychomycosis diagnoses: blastomycosis, invasive aspergillosis that is refractory to or contraindicated to treatment with amphotericin B, allergic bronchopulmonary aspergillosis, fungal vaginitis, histoplasmosis, paracoccidioidomycosis, sporotrichosis, cryptococcus, and coccidioidomycosis.

Onmel will specifically only be approved for onychomycosis after trial and failure of generic itraconazole capsules.

Itraconazole solution is covered with prior authorization for patients who have the following diagnoses: oropharyngeal or esophageal candidiasis.