

## PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>ITRACONAZOLE CAPSULES</b>
<b>BRAND NAME (generic)</b>	<b>SPORANOX ORAL CAPSULES (itraconazole)</b>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Initial Prior Authorization</b>	

### POLICY

#### **FDA-APPROVED INDICATIONS**

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.

#### **Compendial Uses**

- Coccidioidomycosis<sup>2,3</sup>
- Cryptococcosis<sup>2,3</sup>
- Microsporidiosis<sup>2</sup>
- Penicilliosis<sup>2</sup>
- Pityriasis versicolor/Tinea versicolor<sup>2,3</sup>
- Sporotrichosis<sup>2,3</sup>
- Tinea corporis/Tinea cruris, Tinea manuum/Tinea pedis<sup>2,3</sup>

#### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- Patient has one of the following diagnoses: A) Pityriasis versicolor, B) Tinea versicolor, C) Onychomycosis due to tinea that has been confirmed by a fungal diagnostic test

**OR**

- Patient has one of the following diagnoses: A) Blastomycosis, B) Histoplasmosis, C) Aspergillosis, D) Coccidioidomycosis, E) Cryptococcosis, F) Sporotrichosis, G) Penicilliosis, H) Microsporidiosis.

**OR**

- Patient has one of the following diagnoses: A) Tinea corporis, B) Tinea cruris, C) Tinea manuum, D) Tinea pedis.

**AND**

- Patient experienced an inadequate treatment response, adverse event, intolerance, or contraindication to griseofulvin

**REFERENCES**

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8. Kaplan J, Benson C, Holmes K, et al. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents: Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *MMWR Recomm Rep*. 2009;58:1–207.