

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**SPORANOX ORAL CAPSULES**  
(itraconazole)

**Status: CVS Caremark Criteria**  
**Type: Initial Prior Authorization**

## 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, antiinfective 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>

Coccidioidomycosis prophylaxis in HIV infection<sup>2,3</sup>

Cryptococcosis<sup>2,3</sup>

Histoplasmosis prophylaxis in HIV infection<sup>2,3</sup>

Invasive fungal infection prophylaxis in liver transplant patients<sup>3</sup>

Invasive fungal infection prophylaxis in patients with hematologic malignancies<sup>3</sup>

Invasive fungal infection prophylaxis in patients with chronic granulomatous disease<sup>3</sup>

Microsporidiosis<sup>2</sup>

Talaromycosis (formerly Penicilliosis)<sup>2</sup>

Pityriasis versicolor/Tinea versicolor<sup>3</sup>

Sporotrichosis<sup>2,3</sup>

Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis<sup>3</sup>

### COVERAGE CRITERIA

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

- The requested drug is not being used in a footbath

#### **AND**

- The patient has one of the following diagnoses: A) Pityriasis versicolor, B) Tinea versicolor, C) Onychomycosis due to dermatophytes (Tinea unguium) confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH])

preparation, fungal culture, or nail biopsy), D) Tinea corporis, E) Tinea cruris, F) Tinea capitis, G) Tinea manuum, H) Tinea pedis

**OR**

- The patient has one of the following diagnoses: A) Disseminated histoplasmosis, B) Central nervous system (CNS) histoplasmosis, C) Histoplasmosis prophylaxis in HIV infection, D) Coccidioidomycosis prophylaxis in HIV infection, E) Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease

**OR**

- The patient has one of the following diagnoses: A) Blastomycosis, B) Histoplasmosis, C) Aspergillosis in a patient intolerant of or refractory to amphotericin B therapy, D) Coccidioidomycosis, E) Cryptococcosis, F) Sporotrichosis, G) Talaromycosis (formerly Penicilliosis), H) Microsporidiosis, I) Invasive fungal infection prophylaxis in a liver transplant patient, J) Invasive fungal infection prophylaxis in a patient with hematologic malignancy

## **REFERENCES**

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8. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at [http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult\\_oi.pdf](http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf). Accessed February 2021.