

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 cavitory 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^{2,3}

Coccidioidomycosis prophylaxis in HIV infection^{2,3}

Cryptococcosis^{2,3}

Histoplasmosis prophylaxis in HIV infection^{2,3}

Invasive fungal infection prophylaxis in liver transplant patients³

Microsporidiosis²

Talaromycosis (formerly Penicilliosis)²

Pityriasis versicolor/Tinea versicolor³

Sporotrichosis^{2,3}

Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis³

COVERAGE CRITERIA

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

- 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)
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
OR

- The patient has one of the following diagnoses: A) Blastomycosis, B) Histoplasmosis, C) Aspergillosis, D) Coccidioidomycosis, E) Cryptococcosis, F) Sporotrichosis, G) Talaromycosis (formerly Penicilliosis), H) Microsporidiosis, I) Invasive fungal infection prophylaxis in liver transplant patients
- OR**
- The patient has one of the following diagnoses: A) Tinea corporis, B) Tinea cruris, C) Tinea capitis, D) Tinea manuum, E) Tinea pedis
- AND**
- The patient experienced an inadequate treatment response, intolerance, or contraindication to any of the following: A) fluconazole, B) griseofulvin, C) terbinafine

REFERENCES

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3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed February 2020.
4. Patterson TF, Thompson GR, Denning DW, et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2016;63:112–146.
5. Wheat L, Freifeld A, Kleiman M, et al. Clinical Practice Guidelines for the Management of Patients with Histoplasmosis: 2007 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2007;45:807–25.
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7. Perfect J, Dismukes W, Dromer F, et al. Clinical Practice Guidelines for the Management of Cryptococcal Disease: 2010 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2010;50:291–322.
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. Accessed February 2020.
9. Ely, JW, Rosenfeld, S, Stone, MS. Diagnosis and Management of Tinea Infections. *American Family Physician* 2014;90(10):702-712.