

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, 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^{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

Invasive fungal infection prophylaxis in patients with hematologic malignancies³

Invasive fungal infection prophylaxis in patients with chronic granulomatous disease³

Microsporidiosis²

Talaromycosis (formerly Penicilliosis)²

Pityriasis versicolor/Tinea versicolor³

Sporotrichosis^{2,3}

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

Primary Therapy for Allergic Bronchopulmonary Aspergillosis, in combination with systemic corticosteroids^{2,3,4}

Primary Therapy for Chronic Cavitary Pulmonary Aspergillosis^{2,3,4}

COVERAGE CRITERIA

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The patient meets ONE of the following:
 - The requested drug is being prescribed for ANY of the following:

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- Pityriasis versicolor
- Tinea versicolor
- Onychomycosis due to dermatophytes (Tinea unguium) confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
- Disseminated histoplasmosis
- Central nervous system (CNS) histoplasmosis
- Histoplasmosis prophylaxis in HIV infection
- Coccidioidomycosis prophylaxis in HIV infection
- Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease
- Primary therapy for chronic cavitary pulmonary aspergillosis
- Blastomycosis
- Histoplasmosis
- Primary therapy for allergic bronchopulmonary aspergillosis, in combination with systemic corticosteroids
- Aspergillosis in a patient intolerant of or refractory to amphotericin B therapy
- Coccidioidomycosis
- Cryptococcosis
- Sporotrichosis
- Talaromycosis (formerly Penicilliosis)
- Microsporidiosis
- Invasive fungal infection prophylaxis in a liver transplant patient
- Invasive fungal infection prophylaxis in a patient with a hematologic malignancy
- The requested drug is being prescribed for ANY of the following: Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis and the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to ANY of the following: fluconazole, griseofulvin, terbinafine

DURATION OF APPROVAL (DOA)

- 280-A:
 - Pityriasis versicolor, Tinea versicolor, Onychomycosis due to dermatophytes (Tinea unguium), Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis: DOA: 3 months
 - Blastomycosis, Histoplasmosis, Primary therapy for allergic bronchopulmonary aspergillosis, Aspergillosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Talaromycosis (formerly Penicilliosis), Microsporidiosis, Invasive fungal infection prophylaxis in a liver transplant patient, Invasive fungal infection prophylaxis in a patient with a hematologic malignancy: DOA: 6 months
 - Disseminated histoplasmosis, Central nervous system (CNS) histoplasmosis, Histoplasmosis prophylaxis in HIV infection, Coccidioidomycosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease, Primary therapy for chronic cavitary pulmonary aspergillosis: DOA: 12 months

REFERENCES

1. Sporanox capsule [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed February 9, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/09/2024).
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.
6. Chapman S, Dismukes W, Proia L, et al. Clinical Practice Guidelines for the Management of Blastomycosis: 2008 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2008;46:1801–12.

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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: <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf>. Accessed February 12, 2024.
9. Ely, JW, Rosenfeld, S, Stone, MS. Diagnosis and Management of Tinea Infections. *American Family Physician*. 2014;90(10):702-712.