Reference number(s)
280-A

Initial Prior Authorization
Sporanox Oral Capsules

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Sporanox	itraconazole	oral capsules

Indications

FDA-approved Indications

Sporanox (itraconazole) Capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- 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:

- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
- 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 patients[3]

Invasive fungal infection prophylaxis in patients with hematologic malignancies[3]

Invasive fungal infection prophylaxis in patients with chronic granulomatous disease[3]

Microsporidiosis[2]

Talaromycosis (formerly Penicilliosis)[2]

Pityriasis versicolor/Tinea versicolor[3]

Sporotrichosis[2,3]

Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis[3]

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:
        - 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)
        - 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, 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
  - 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.; December 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed January 29, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/17/2025).

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.
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/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new?view=full. Accessed January 30, 2025.
9. Ely, JW, Rosenfeld, S, Stone, MS. Diagnosis and Management of Tinea Infections. American Family Physician. 2014;90(10):702-712.

Document History

Written by: UM Development (SE)

Date written: 12/2009

Revised: (KD/SE) CAS Adapted 09/2010, (TM) 08/2011; (RP) 08/2012; (PL) 08/2013, 08/2014; (MS) 05/2015, 05/2016 (no clinical changes), (SE) 06/2016 (created separate Med D); (MS) 04/2017; (DS) 04/2018, (ME) 02/2019 (no clinical changes), 02/2020, (NZ) 02/2021 (added compendial uses and footbath question), (DFW) 02/2022 (added ABPA and CCPA compendial uses), (VLS) 02/2023 (no clinical changes), 02/2024 (no clinical changes), ANB 02/2025 (updated DOA to 12 months for all types of histoplasmosis)

Reviewed: Medical Affairs (KP) 12/2009, (KP) 07/2010, (KP) 08/2011; (DC) 08/2012; (DNC) 08/2013; (LCB) 08/2014; (LS) 05/2015; (AN) 04/2017; (DNC) 04/2018, (CHART) 02/27/20, 02/25/2021, 02/24/2022, 02/23/2023, 02/29/2024, 02/27/2025, 04/17/2025

External Review: 02/2010, 12/2010, 10/2011, 12/2011, 12/2012, 12/2013, 10/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

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1	Is the requested drug being used in a footbath? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the requested drug being prescribed for any of the following: 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)? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Is the requested drug being prescribed for any of the following: A) Tinea corporis, B) Tinea cruris, C) Tinea capitis, D) Tinea manuum, E) Tinea pedis? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Has the patient experienced an inadequate treatment response, intolerance or does the patient have a contraindication to any of the following: A) fluconazole, B) griseofulvin, C) terbinafine? [No further questions]	Yes	No
5	Is the requested drug being prescribed for any of the following: A) Histoplasmosis, B) Histoplasmosis prophylaxis in HIV infection, C) Coccidioidomycosis prophylaxis in HIV infection, D) Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease, E) Primary therapy for chronic cavitary pulmonary aspergillosis? [If Yes, then no further questions. If No, then go to 6.]	Yes	No
6	Is the requested drug being prescribed for any of the following: A) Blastomycosis, B) Primary therapy for allergic bronchopulmonary aspergillosis, in combination with systemic corticosteroids, 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 a hematologic malignancy? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Deny	Go to 2	We have denied your request because your plan does not cover this drug for use in a footbath. We reviewed the information we had. Your request has been denied. Your doctor can send us any

			new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exclusion]
2.	Approve, 3 Months	Go to 3	
3.	Go to 4	Go to 5	
4.	Approve, 3 Months	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried fluconazole, griseofulvin, or terbinafine and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
5.	Approve, 12 Months	Go to 6	
6.	Approve, 6 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for treating or preventing specific fungal infections. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]

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