

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

SPORANOX ORAL CAPSULES
(itraconazole)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

MDC-1
Ref # 280 -A

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated

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}
- Cryptococcosis^{2,3}
- Microsporidiosis²
- Penicilliosis²
- Pityriasis versicolor/Tinea versicolor^{2,3}
- 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:

- 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 capitis, D) Tinea manuum, E) Tinea pedis
AND

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

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The criteria do not provide treatment for cosmetic purposes. Sporanox (itraconazole) capsules are indicated for the treatment of 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, anti-infective therapy should be adjusted accordingly. Acceptable compendia also indicate that itraconazole is appropriate for the treatment of coccidioidomycosis, cryptococcosis, sporotrichosis, penicilliosis, and microsporidiosis.^{2,3,7,8} Sporanox capsules are also indicated in non-immunocompromised patients for the treatment of 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 potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy should be obtained to confirm the diagnosis of onychomycosis. Per the compendia, itraconazole is suggested as an alternative therapy for the treatment of pityriasis versicolor or tinea versicolor, tinea corporis, tinea cruris, tinea capitis, tinea manuum or tinea pedis.^{2,3}

Itraconazole will be approved for the treatment of onychomycosis due to dermatophytes (*tinea unguium*) following confirmation with a fungal diagnostic test (e.g., KOH preparation, fungal culture, or nail biopsy). Itraconazole will be approved for the treatment of patients with either pityriasis versicolor or tinea versicolor. Itraconazole will be approved for the treatment of tinea corporis, tinea cruris, tinea capitis, tinea manuum or tinea pedis following a trial of griseofulvin as it is FDA approved as first line therapy. Itraconazole will be approved for the treatment of blastomycosis, histoplasmosis, aspergillosis, coccidioidomycosis, cryptococcosis, sporotrichosis, penicilliosis, and microsporidiosis.

The recommended treatment course for onychomycosis of the toenails, with or without fingernail involvement, is 200 mg once daily for 12 weeks.¹ The suggested dosing for superficial tinea infections is similar to that of onychomycosis of the toenails, 200 mg once daily, although for a shorter duration.³ Therefore, coverage for these conditions will be approved for up to 3 months. The recommended and suggested treatments for the remainder of the approvable indications vary depending on the type of infection and patient specific factors. It is noted, however, that treatment in life-threatening situations should be continued for a minimum of 3 months and until clinical parameters and laboratory tests indicate that the active fungal infection has subsided. An inadequate period of treatment may lead to recurrence of active infection.¹ Because of this, the duration of approval for these indications will be set at 6 months.

REFERENCES

1. Sporanox capsule [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 2018.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 2018.
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 http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed April 2018.

Written by: UM Development (SE)
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 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
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 External Review: 02/2010, 12/2010, 10/2011, 12/2011, 12/2012, 12/2013, 10/2014, 10/2015, 08/2016, 08/2017, 06/2018

CRITERIA FOR APPROVAL

1	Does the patient have 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? [If yes, then no further questions.]	Yes	No
2	Does the patient have one of the following diagnoses: A) Tinea corporis, B) Tinea cruris, C) Tinea capitis, D) Tinea manuum, E) Tinea pedis? [If no, then skip to question 4.]	Yes	No
3	Has the patient experienced an inadequate treatment response, adverse event, intolerance, or contraindication to griseofulvin? [No further questions.]	Yes	No
4	Does the patient have one of the following diagnoses: A) Blastomycosis, B) Histoplasmosis, C) Aspergillosis, D) Coccidioidomycosis, E) Cryptococcosis, F) Sporotrichosis, G) Penicilliosis, H) Microsporidiosis?	Yes	No

Guidelines for Approval

Duration of Approval		3 Months	
Set 1		Set 2	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	2	1
		3	
Duration of Approval		6 Months	
Set 3			
Yes to question(s)	No to question(s)		
4		1	
		2	

Mapping Instructions

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 3 months	Go to 2	
2.	Go to 3	Go to 4	
3.	Approve, 3 months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have these conditions:</p> <ul style="list-style-type: none"> - You have ringworm, a fungal infection of the groin, scalp, or hand, or athlete’s foot - You had a poor response to griseofulvin or cannot take it. <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis, no inadequate response, intolerance or contraindication to griseofulvin]</p>
4.	Approve, 6 months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have one of these conditions:</p> <ul style="list-style-type: none"> - You have an fungal infection of the skin that causes spots - You have nail fungus and it has been tested - You have Blastomycosis, Histoplasmosis, Aspergillosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Penicilliosis or Microsporidiosis <p>Your request has been denied based on the information we have. .</p> <p>[Short Description: No approvable diagnosis, no confirmation of diagnosis]</p>