PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

SPORANOX ORAL SOLUTION
(itraconazole)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 1286-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) Oral Solution is indicated for the treatment of oropharyngeal and esophageal candidiasis.

COMPENDIAL USES

- Blastomycosis[3,4]
- Histoplasmosis[3,4]
- Aspergillosis [3,4]
- Coccidioidomycosis[3,4]
- Cryptococcosis[3,4]
- Microsporidiosis[3]
- Penicilliosis[3]
- Pityriasis versicolor/Tinea versicolor[4]
- Sporotrichosis[3,4]
- Tinea corporis/Tinea cruris, Tinea capitis, Tinea manuum/Tinea pedis[4]

COVERAGE CRITERIA

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

- Patient has a diagnosis of oropharyngeal candidiasis or esophageal candidiasis.
  OR
- Patient is unable to take itraconazole capsules due to one of the following: inability to swallow itraconazole capsules or inability to achieve therapeutic levels with itraconazole capsules.
  AND
- 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

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. Sporanox (itraconazole) Oral Solution is indicated for the treatment of oropharyngeal and esophageal candidiasis.

For oropharyngeal candidiasis, Sporanox (itraconazole) Oral Solution should be taken for 1 to 2 weeks. For patients with oropharyngeal candidiasis unresponsive/refractory to treatment with fluconazole tablets responding to Sporanox (itraconazole) Oral Solution therapy, clinical response will be seen in 2 to 4 weeks. Patients may be expected to relapse shortly after discontinuing therapy. There is limited data on the safety of long-term use, greater than 6 months, of Sporanox (itraconazole) Oral Solution. For esophageal candidiasis, Sporanox (itraconazole) Oral Solution should be taken for a minimum treatment of 3 weeks. Treatment should continue for 2 weeks following resolution of symptoms. Sporanox (itraconazole) Oral Solution and Sporanox (itraconazole) Capsules should not be used interchangeably as only Sporanox (itraconazole) Oral Solution has been demonstrated effective for oral and/or esophageal candidiasis.[1-4]

Although it is not recommend to use Sporanox (itraconazole) capsules interchangeably with Sporanox (itraconazole) Oral Solution for the treatment or oral and/or esophageal candidiasis, it is reasonable to assume that the interchange can work in the opposite direction. That is to say, Sporanox (itraconazole) Oral Solution can be approved for the same indications/compendia uses as Sporanox (itraconazole) capsules. For these uses, the patient must be unable to take the capsules (due to an inability to swallow or achieve therapeutic levels with itraconazole capsules). The criteria do not provide treatment for cosmetic purposes. Itraconazole can be used 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.[2,-4] 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 show that itraconazole is appropriate for the treatment of coccidioidomycosis, cryptococcosis, sporotrichosis, penicilliosis, and microsporidiosis. Itraconazole can also be used 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).[3,4,9,10] 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.[3,4]

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.[2] 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.[4] 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.[2] Because of this, the duration of approval for these indications will be set at 6 months.

REFERENCES

1. Sporanox Oral Solution [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2017.
2. Sporanox Capsule [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2017.
3. 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.
4. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 2018.
5. Pappas P, Kauffman C, Andes D, et al. Clinical Practice Guidelines for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2016;62:1-50.

6. 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.
7. 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.
8. 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.
9. 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.
10. 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.

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CRITERIA FOR APPROVAL

1	Does the patient have one of the following diagnoses: A) Oropharyngeal candidiasis, B) Esophageal candidiasis? [If yes, then no further questions.]	Yes	No
2	Is the patient unable to take itraconazole capsules due to one of the following: A) inability to swallow itraconazole capsules, B) inability to achieve therapeutic levels with itraconazole capsules?	Yes	No
3	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
4	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 6.]	Yes	No
5	Has the patient experienced an inadequate treatment response, adverse event, intolerance, or contraindication to griseofulvin? [No further questions.]	Yes	No
6	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

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 6 months	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet one of these conditions: - You have a fungal infection of the mouth or throat (Oropharyngeal candidiasis or Esophageal candidiasis) - You are unable to swallow capsules - You are unable to get a strong enough dose with capsules Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no justification for solution over capsules]
3.	Approve, 3 months	Go to 4	
4.	Go to 5	Go to 6	
5.	Approve, 3 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have these conditions: - 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 Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no inadequate response, intolerance or contraindication to griseofulvin]
6.	Approve, 6 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have one of these conditions: - 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 Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no confirmation of diagnosis]