PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

SPORANOX ORAL SOLUTION
(itraconazole)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 210-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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

COVERAGE CRITERIA

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

- The patient has a diagnosis of oropharyngeal candidiasis or esophageal candidiasis

AND

- The patient has experienced an inadequate treatment response to fluconazole
  OR
- The patient has experienced an intolerance to fluconazole
  OR
- The patient has a contraindication that would prohibit a trial of fluconazole

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.[1]

The Infectious Diseases Society of America (IDSA) recommends clotrimazole, miconazole or nystatin for mild oropharyngeal candidiasis. For mild disease, clotrimazole troches or miconazole buccal tablets are recommended. Alternatives for mild disease include nystatin suspension. For moderate to severe oropharyngeal candidiasis, oral fluconazole is recommended. For fluconazole-refractory disease, itraconazole solution or posaconazole suspension are recommended. Fluconazole-refractory infections should be treated initially with itraconazole solution; between 64% and 80% of patients will respond to this therapy. Posaconazole suspension is efficacious in approximately 75% of patients with refractory oropharyngeal candidiasis. Itraconazole is only available in oral formulations. It has not been well studied for invasive candidiasis, and is generally reserved for patients with mucosal candidiasis, especially those who have experienced treatment failure with fluconazole.[4] Fluconazole is FDA-approved for the treatment of oropharyngeal and esophageal candidiasis. Itraconazole will be approved for the treatment of oropharyngeal or esophageal candidiasis following an inadequate treatment response or intolerance to fluconazole, or for patients who have a contraindication to fluconazole.

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. 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 Oral Solution and Sporanox Capsules should not be used interchangeably. Only Sporanox Oral Solution has been

demonstrated effective for oral and/or esophageal candidiasis. There is limited data on the safety of long-term use, greater than 6 months, of Sporanox Oral Solution. There is limited data on the safety of long-term use, greater than 6 months, of Sporanox Oral Solution.[1] Therefore, the duration of approval will be set at 6 months.

REFERENCES

1. Sporanox Oral Solution [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc. 2021. Accessed January 12, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 12, 2021.
4. 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**.**

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Date Written: 12/2005
Revised: (NB) 08/2006, 07/2007, (MS) 07/2008, (SE) 07/2009, (TM) 07/2010, 08/2011; (RP) 08/2012; (PL) 08/2013, 08/2014; (MS) 05/2015, 08/2015 (changed to MDC-2), 05/2016 (no clinical changes), 04/2017; (DS) 04/2018 (no clinical changes), (ME) 02/2019 (no clinical changes), 02/2020 (removed MDC designation from title/document), (NZ) 02/2021 (added t/f of fluconazole)
Reviewed: Medical Affairs (MM) 12/2005, 08/2006, (WF) 07/2007, (WF) 07/2008, 07/2009, (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
External Review: 04/2006; 12/2006; 02/2008; 10/2008, 10/2009, 12/2010, 12/2011, 12/2012, 12/2013, 10/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020,06/2021

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of oropharyngeal candidiasis or esophageal candidiasis? [If no, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to fluconazole? [If yes, then no further questions.]	Yes	No
3	Has the patient experienced an intolerance to fluconazole? [If yes, then no further questions.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of fluconazole?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have a fungal infection of the mouth or throat (Oropharyngeal candidiasis or Esophageal candidiasis). Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Approve, 6 months	Go to 3	
3.	Approve, 6 months	Go to 4	
4.	Approve, 6 months	Deny	You do not meet requirements of your plan. Your plan covers this drug when you have tried fluconazole and it did not work for you or you cannot use it. [Short Description: No inadequate response, intolerance or contraindication to fluconazole]