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

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. 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. 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: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed February 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed February 2020.
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.

Written by:	UM Development (CT)
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)
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 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

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of oropharyngeal candidiasis or esophageal candidiasis?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 6 months	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]