Reference number(s)
210-A

Initial Prior Authorization
Sporanox Oral Solution

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 solution

Indications

FDA-approved Indications

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

Coverage Criteria

Esophageal Candidiasis, Oropharyngeal Candidiasis

Authorization may be granted when the requested drug is being prescribed for the treatment of esophageal candidiasis or oropharyngeal candidiasis when ONE of the following criteria are met:

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

Reference number(s)
210-A

Duration of Approval (DOA)

- 210-A: DOA: 6 months

References

1. Sporanox Oral Solution [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: 01/017/2025).
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.

Document History

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), (NZ) 02/2021 (added t/f of fluconazole), (DFW) 02/2022 (no clinical changes), (VLS) 02/2023 (no clinical changes), 02/2024 (no clinical changes), ANB 02/2025 (no clinical changes)

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, 02/24/2022, 02/23/2023, 02/29/2024, 02/27/2025

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, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of oropharyngeal candidiasis or esophageal candidiasis? [If Yes, then go to 2. 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. If No, then go to 3.]	Yes	No
3	Has the patient experienced an intolerance to fluconazole? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of fluconazole? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for treatment of fungal infections of the mouth or throat. 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]
2.	Approve, 6 Months	Go to 3	
3.	Approve, 6 Months	Go to 4	
4.	Approve, 6 Months	Deny	Your plan only covers this drug if you have tried fluconazole, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. 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]