PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

SPORANOX ORAL SOLUTION (itraconazole)

Status: CVS Caremark® Criteria Type: Initial Prior Authorization

POLICY

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

DURATION OF APPROVAL (DOA)

210-A: DOA: 6 months

REFERENCES

- 1. Sporanox Oral Solution [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed February 9, 2024.
- 3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/09/2024).
- 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.

Itraconazole (Sporanox Oral Solution) PA Policy UDR 03-2024.docx

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