Clinical Policy: itraconazole (Sporanox)
Reference Number: HIM.PA.36
Effective Date: 05/16
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Itraconazole (Sporanox®) is an azole antifungal agent.

**FDA approved indication**
Sporanox capsule is indicated:

- For the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:
  - 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.
- For the treatment of the following fungal infections in non-immunocompromised patients:
  - Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
  - Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

Sporanox oral solution is indicated for the treatment of oropharyngeal and esophageal candidiasis.

**Policy/Criteria**
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

**I. Initial Approval Criteria**

**A. Onychomycosis** (must meet all)**:**
1. Diagnosis of onychomycosis;
2. Member meets one of the following ( a or b):
   a. For fingernail disease: Failure of a 6 week trial of oral terbinafine at 250 mg/day unless contraindicated or clinically significant adverse effects are experienced;
   b. For toenail disease: Failure of a 12 week trial of oral terbinafine at 250 mg/day unless contraindicated or clinically significant adverse effects are experienced;
3. Request is for Sporanox capsules;
4. Dose does not exceed 400 mg per day (4 capsules/day).

**Approval duration: Fingernails only: 2 months; Toenails: 3 months**

**B. Oropharyngeal Candidiasis** (must meet all)**:**
1. Diagnosis of oropharyngeal candidiasis;

2. Request is for Sporanox oral solution;
3. Failure of a 14 day trial of nystatin suspension or clotrimazole troches/lozenges unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of a 14 day treatment course of fluconazole unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 200mg (20 mL) per day.

**Approval duration: 4 weeks**

**C. Esophageal Candidiasis** (must meet all)**:**

1. Diagnosis of esophageal candidiasis;
2. Request is for Sporanox oral solution;
3. Failure of a 21 day treatment course of oral fluconazole unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 200 mg (20mL) per day.

**Approval duration: 4 weeks**

**D. Aspergillosis** (must meet all):

1. Diagnosis of aspergillosis;
2. Failure of a 3 month trial of voriconazole at maximally indicated dose unless contraindicated or clinically significant adverse effects are experienced;
3. Request is for Sporanox capsules;
4. Dose does not exceed 400 mg per day (4 capsules/day);

**Approval duration: 3 months**

**E. Blastomycosis or Histoplasmosis**

1. Diagnosis of blastomycosis or histoplasmosis;
2. Request is for Sporanox capsules;
3. Dose does not exceed 400 mg per day (4 capsules/day).

**Approval duration: Blastomycosis: 6 months; Histoplasmosis: 6 weeks**

**F. Other diagnoses/indications**

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

## II. Continued Therapy

**A. Onychomycosis** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Dose does not exceed 400 mg per day (4 capsules/day);
3. Member has not received more than 90 days of treatment.

**Approval duration: Allow 2 months of total treat for fingernails; Allow 3 months of total treatment for toenails**

**B. Oropharyngeal Candidiasis /Esophageal Candidiasis** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg (20 mL) per day.

**Approval duration: 2 weeks**

**C. Blastomycosis, Histoplasmosis, or Aspergillosis** (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg per day (4 capsules per day).

**Approval duration: Blastomycosis 6 months; Histoplasmosis 6 weeks; Aspergillosis 6 weeks**

**D. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

## IV. Appendices/General Information

*Appendix A: Abbreviation Key*

FDA: Food and Drug Administration

## V. References

1. Sporanox® capsules, oral solution prescribing information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2016. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020083s058,020657s033lbl.pdf. Accessed January 11, 2017.
2. Sporanox® monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com
3. Sporanox® monograph. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 11, 2017
4. Pappas PG, Kauffman CA, Andes D, et al. Guidelines for the Management of Candidiasis. Clin Infect Dis; 2009; 48: 503 -535.
5. Freifeld AG, Bow EJ, Sepkowitz KA, et al. Guidelines for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer. Clinical Infectious Diseases; 2010; 52(4):e56.
6. Chapman SW, Dismukes WE, Proia LA, et al. Clinical Practice Guidelines for the Management of Blastomycosis. Clinical Infectious Diseases; 2008; 46: 1801 -1812.

7. Walsh TJ, Anaissie EJ, Denning DW, et al. Treatment of Aspergillosis. Clinical Infectious Diseases; 2008; 46: 327 -360
8. Wheat LJ, Freifeld AG, Kleiman MB, 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 -825.
9. Ameen M, Lear JT, Madan V, et al. British Association of Dermatologists' guidelines for the management of Onychomycosis 2014. Br J Dermatology. 2014;171:937-58.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Changed guidelines to new format. Renumbered guideline from HIM.PPA.07 to HIM.PA.36 | 05/16 | 05/16 |
| Converted to new template<br>Clinical changes to criteria<br>- Added 6 week trial of terbinafine for fingernails and 12 week trial of terbinafine for toenail onychomycosis.<br>- Removed requirement of multiple toes and/or fingers involved or member having a diagnosis of diabetes mellitus, peripheral vascular disease, or is immunocompromised for onychomycosis per specialist feedback.<br>- Allow 2 months of total treat for fingernails and 3 months of total treatment for toenails<br>- Separated initial criteria for oropharyngeal and esophageal candidiasis. Esophageal candidiasis requires a trial of fluconazole only per IDSA guidelines.<br>- Added 14 day duration of nystatin or clotrimazole trial and fluconazole trial for oropharyngeal candidiasis per IDSA guideline.<br>- Added 21 day duration of fluconazole trial for esophageal candidiasis per IDSA guideline.<br>- Changed approval duration from 8 weeks to 4 weeks for oropharyngeal and esophageal candidiasis per IDSA guideline and PI.<br>- Changed continued approval duration for oropharyngeal and esophageal candidiasis from 8 weeks to 2 weeks per IDSA guideline and PI.<br>-Separated criteria for aspergillosis and added trial of voriconazole per IDSA guidelines.<br>- Added Request is for Sporanox capsules for onychomycosis, blastomycosis, histoplasmosis, and aspergillosis.<br>- Clarified continued approval duration for blastomycosis, histoplasmosis, and aspergillosis per IDSA guidelines.<br>- Added continued approval criteria for onchomycosis.<br>- Removed indications for mold and candida prophylaxis in neutropenic patients. | 01/17 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their

representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.