Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 6/1/2018**
Policy Number: : PA.CP.PPA.07	**Effective Date: 01/01/2018** **Revision Date: 04/18/2018**
Policy Name: Itraconazole (Sporanox)	**HC Approval Date:**

Type of Submission – Check all that apply:

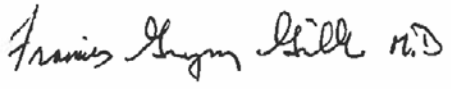
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

- **PA.CP.PMN.124 Itraconazole (Sporanox)**

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Itraconazole (Sporanox)

Reference Number: PA.CP.PPA.07
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

FDA approved indication
Sporanox capsules are indicated in immunocompromised and non-immunocompromised patients:

- For the treatment of blastomycosis, pulmonary and extrapulmonary
- For the treatment of histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
- For the treatment of aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy

Sporanox capsules are indicated in non-immunocompromised patients:

- For the treatment of onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium)
- For the treatment of 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

It is the policy of Pennsylvania Health and Wellness ® that Sporanox is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of onychomycosis;
2. Request is for Sporanox capsules;
3. 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;
4. Dose does not exceed 400 mg per day (4 capsules per 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 trial of fluconazole unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 200 mg (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 trial of fluconazole at maximally indicated dose unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 200 mg (20 mL) per day.

Approval duration: 4 weeks

D. Blastomycosis, Histoplasmosis, or Aspergillosis (must meet all)**:**

1. Diagnosis of blastomycosis, histoplasmosis, or aspergillosis;
2. Request is for Sporanox capsules;
3. Dose does not exceed 400 mg per day (4 capsules per day) with an approval of 600mg per day for first 3 days of treatment for aspergillosis.

Approval duration: Blastomycosis: 6 months; Histoplasmosis: 6 months; Aspergillosis: 3 months

E. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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/Esophageal Candidiasis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 months; Aspergillosis: 3 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 6 months

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 – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Blastomycosis	200 mg once daily	400 mg daily
Histoplasmosis	200 mg once daily	400 mg daily
Aspergillosis	200 to 400 mg daily	400 mg daily
Onychomycosis	200 mg once daily (toenails with or without fingernail involvement) 200 mg PO twice daily for 1 week, followed by no drug for 3 weeks, then another week of 200 mg PO twice daily or 200mg daily for 6 weeks (fingernails only)	400 mg daily

Oropharyngeal candidiasis	200 mg (20 mL) daily for 1 to 2 weeks; swish in the mouth (10 mL at a time) for several seconds and swallow	200 mg (20 mL) daily
Esophageal candidiasis	100 mg (10 mL) daily for a minimum treatment of three weeks	200 mg (20 mL) daily
In life-threatening situations	*Loading dose of 200 three times daily given for the first 3 days of treatment*	*600 mg daily*

VI. Product Availability

Capsules: 100 mg
Oral solution: 10 mg/mL

VII. References

1. Sporanox Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2015. Available at: http://www.janssen.com/us/sites/www_janssen_com_usa/files/products-documents/040501150916_sporanox_oral_solution_eos_code_update_only_sept_20151.pdf. Accessed January 2017.
2. Sporanox oral solution Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc., October 2016. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ae50721d-ee15-4ee7-9fe7-afd98c56461b. Accessed January 2017.
3. Sporanox® monograph. Clinical Pharmacology. Accessed January 2017.
4. Chapman SW, Dismukes WE, Proia LA et al. Clinical practice guidelines for the management of blastomycosis: 2008 update by the Infectious Diseases Society of America. Clin Infect Dis. 2008;46(12):1801.
5. Pappas PG, Kauffman CA, Andes DR et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Disease Society of America. Clin Infect Dis. 2016 Feb 15;62(4):e1-50. doi: 10.1093/cid/civ933.
6. 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. Clin Infect Dis. 2007;45(7):807.
7. Patterson TF, Thompson GR, Denning DW et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2016 Aug 15;63(4):e1-e60. doi: 10.1093/cid/ciw326.
8. 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