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# 5.01.18

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2019
<b>Subsection:</b>	Anti-infective Agents	<b>Original Policy Date:</b>	July 1, 2001
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**Last Review Date:** November 30, 2018

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## Sporanox Onmel

### Description

Sporanox (itraconazole); Onmel (itraconazole)

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### Background

Itraconazole is an antifungal agent used to treat certain fungal infections which include the following: infections of the nails, skin, hands, feet or groin; candida (yeast) infections of the vagina; eye infections which have not responded to other treatment or which may be affecting vision; candida (yeast) infections of the mouth or throat in patients with lower resistance to disease; Itraconazole inhibits the production of ergosterol, which is a vital component of fungal cell membranes and without it causes cell death stopping the growth of the fungus (1).

### Regulatory Status

FDA-approved indication: Sporanox (itraconazole) Oral Solution is indicated for the treatment of oropharyngeal and esophageal candidiasis (1).

Sporanox Capsules are indicated for the treatment of Blastomycosis, Histoplasmosis and Aspergillosis in immunocompromised and non-immunocompromised patients. The capsules are also indicated for the treatment of onychomycosis in non-immunocompromised patients (2).

Do not administer itraconazole for the treatment of onychomycosis in patients with evidence of ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF (1-3).

There are three major forms of aspergillosis: invasive, saprophytic and allergic. The Infectious Disease Society of America (IDSA) recommends the use of itraconazole and corticosteroids for the treatment of allergic bronchopulmonary aspergillosis (4).

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The safety and efficacy of itraconazole in patients less than 18 years of age have not been established (1-3).

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Itraconazole may be considered **medically necessary** in patients 18 years of age and older for the treatment of susceptible fungal infections and if the conditions indicated below are met.

Itraconazole may be considered **investigational** for patients below 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following

1. Onychomycosis
  - a. Not immunocompromised
  - b. Not have evidence of ventricular dysfunction, such as congestive heart failure or a history of CHF
2. Candidiasis
  - a. Must be unresponsive to Fluconazole
  - b. Includes oropharyngeal and esophageal candidiasis
3. Aspergillosis – invasive or saprophytic
  - a. Must be refractory or intolerant to amphotericin B
4. Aspergillosis - allergic bronchopulmonary
5. Blastomycosis
6. Coccidioidomycosis
7. Histoplasmosis
8. Sporotrichosis
9. Other diagnosed fungal infection **and** diabetic or immune compromised

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## **Prior – Approval *Renewal* Requirements**

Same as above

### **Policy Guidelines**

#### **Pre - PA Allowance**

None

#### **Prior - Approval Limits**

**Duration** 6 months for a diagnosis of Onychomycosis or Candidiasis  
1 year for all other diagnoses **or** if diabetic or immune compromised

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#### **Prior – Approval *Renewal* Limits**

**Duration** 6 months for a diagnosis of Onychomycosis or Candidiasis  
1 year for all other diagnoses **or** if diabetic or immune compromised

### **Rationale**

#### **Summary**

Sporanox (itraconazole) is an antifungal agent. Itraconazole inhibits the production of ergosterol, which is a vital component of fungal cell membranes. The safety and efficacy of itraconazole in patients less than 18 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of SporanoX while maintaining optimal therapeutic outcomes.

#### **References**

1. SporanoX oral solution [package insert]. Titusville, NJ: Janssen Pharmaceuticals; March 2017.
2. SporanoX capsules [package insert]. Titusville, NJ: Janssen Pharmaceuticals; March 2017.
3. Onmel [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; November 2012.
4. 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. *Clinical Infectious Diseases*. 2016; 63:112-146.

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## Policy History

Date	Action
December 2012	Annual editorial review and reference update.
March 2013	Addition of age and contraindication for CHF Addition of Onmel as a line extension
September 2014	Annual editorial review and reference update
September 2015	Annual editorial review and reference update Addition of identified types of aspergillosis- allergic bronchopulmonary and aspergillosis – invasive or saprophytic
March 2016	Annual editorial review Policy number changed from 5.03.18 to 5.01.18
December 2017	Annual editorial review and reference update
November 2018	Annual editorial review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on November 30, 2018 and is effective on January 1, 2019.**