

**Sporanox® (itraconazole) oral solution  
Itraconazole capsules  
Effective 11/26/18**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	Sporanox® (itraconazole) oral solution has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

Sporanox® (itraconazole) oral solution and itraconazole capsules are inhibitor of CYP450-dependent synthesis of ergosterol.

Sporanox® (itraconazole) oral solution is indicated for the treatment of oral and/or oesophageal candidiasis in HIV-positive or other immunocompromised patients and prophylaxis of fungal infections in neutropenic patients.

Itraconazole capsules are indicated for the treatment of:

1. Superficial dermatomycoses not responding to topical treatment.
2. Fungal keratitis which has failed to respond to topical treatment or where the disease is either progressing rapidly or is immediately sight threatening.
3. Pityriasis versicolor not responding to any other treatment.
4. Vulvovaginal candidiasis not responding to topical treatment.
5. Oral candidiasis in immunocompromised patients.
6. Onychomycosis caused by dermatophytes.
7. Systemic mycoses, only in the following fungal infections:
  - a. Systemic aspergillosis, histoplasmosis, lymphocutaneous/cutaneous sporotrichosis.
  - b. Treatment and maintenance therapy in AIDS patients with disseminated or chronic pulmonary histoplasmosis infection.
  - c. Treatment of oropharyngeal and/or oesophageal candidiasis when first line systemic antifungal therapy is inappropriate or has proven ineffective.

- d. Treatment of non-invasive candidiasis in non-neutropenic patients when first-line systemic antifungal therapy is inappropriate or has proven ineffective. This may be due to underlying pathology, insensitivity of the pathogen or drug toxicity.

## Coverage Guidelines

### Sporanox® (itraconazole) oral solution 10 mg/mL

Authorization may be granted for members when ALL the following criteria are met:

1. Member has required treatment of oropharyngeal candidiasis or esophageal candidiasis.
2. Prescriber has provided documentation of a treatment failure or contraindication with oral fluconazole 200mg daily or greater.
3. Prescriber has provided documentation of ONE of the following:
  - a. Member is 6 years of age or younger.
  - b. Member has an inability to swallow capsules (i.e. dysphagia).

### Itraconazole 100mg capsules

Authorization may be granted for members when product is being used for the one of the following conditions **AND** documentation (clinical notes and diagnostic confirmations) have been submitted:

1. Allergic bronchopulmonary aspergillosis
2. Allergic aspergillus sinusitis
3. Treatment of onychomycosis/tinea unguium (toenail and/or fingernail infection) caused by candida species
4. Treatment of onychomycosis/tinea unguium (toenail and/or fingernail infection) caused by non-candida species in a patient who:
  - a. Has tried and failed terbinafine **AND**
  - b. Is immunocompromised, has diabetes or has pain/mobility issues
5. Treatment of vaginal candidiasis in a patient who has tried and failed a topical vaginal antifungal **AND** fluconazole single-dose 150 mg
6. Treatment of tinea versicolor (pityriasis versicolor) in a patient who has tried and failed a topical antifungal agent\*, oral fluconazole **AND** oral ketoconazole
  - a. Note: Trial of a topical antifungal agent may be bypassed if the infection involves a large area of the body that which would be difficult to treat with a topical agent\*
7. Treatment of tinea capitis or tinea barbae (tinea sycosis) in a patient who has tried and failed oral griseofulvin
8. Treatment of tinea cruris, tinea faciei, or tinea manuum (tinea manus) in a patient who has tried and failed a topical antifungal agent
9. Treatment of tinea corporis (ring worm) in a patient who has tried and failed a topical antifungal agent\* **AND** oral fluconazole
  - a. Note: Trial of a topical antifungal agent may be bypassed if the infection involves a large area of the body that which would be difficult to treat with a topical agent\*
10. Treatment of tinea imbricata in a patient who has tried and failed **either** oral griseofulvin **OR** terbinafine
11. Treatment of tinea pedis in a patient who either:
  - a. Has tried and failed a topical antifungal agent **OR**
  - b. Has plantar-type or moccasin-type dry chronic tinea pedis
12. Treatment of oropharyngeal candidiasis (oral thrush) in a patient who has tried and failed oral fluconazole at a daily dose  $\geq 200$  mg

13. Prevention of other systemic or superficial fungal infections in an immunocompromised patient who has tried and failed oral fluconazole (if appropriate for indication)
14. Treatment of other systemic or superficial fungal infections in a patient who has tried and failed oral fluconazole (if appropriate for indication)

### Limitations

1. For Sporanox®, authorization will be for 450mL (200mg daily) for 21 days.
2. For Itraconazole 100mg capsules, AllWays Health Partners allows a maximum of 170 capsules per 12 months.
  - a. The following quantity and timeframe limits apply:

Indication	Approved Quantity/Duration
Allergic bronchopulmonary aspergillosis	60 capsules per month for 180 days
Allergic aspergillus sinusitis	
Prevention/treatment of other systemic or superficial fungal infections in an immunocompromised person	
Onychomycosis (fingernail)	14 capsules per month for 2 months  <u>Dosing:</u> 200 mg twice daily for 1 week; repeat 1-week course after 3-week off-time
Onychomycosis (toenail involvement)	Pulse therapy: 14 capsules per month for 3 months
	<u>Dosing:</u> 200 mg twice daily for 1 week; repeat 1-week course after 3-week off-time
	Standard therapy: 60 capsules per month for 12 consecutive weeks
Tinea versicolor (Pityriasis versicolor)	14 capsules for 7 days
All other indications	60 capsules per month

### References

1. Gupta AK, Mays RR, Versteeg SG, et al. Tinea capitis in children: a systematic review of management. *J Eur Acad Dermatol Venereol* 2018;4.
2. Sporanox (itraconazole) oral solution [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; April 2018
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17. Akhtar S, Masood S, Tabassum S, et al. Efficacy of itraconazole versus fluconazole in vaginal candidiasis. *J Pak Med Assoc*. 2012 Oct;62(10):1049-52.
18. Goldstein BG, Goldstein AO. Tinea Versicolor. In: Basow DS. UpToDate [database on the internet]. Waltham (MA): UpToDate; 2014. Available at: <http://www.utdol.com/utd/index/do>
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## Review History

12/19/05 – Reviewed  
11/27/06 – Reviewed  
11/26/07 – Reviewed and updated  
11/24/08 – Reviewed  
11/23/09 – Reviewed and updated (oral thrush criteria)  
11/22/10 – Reviewed and updated  
11/28/11 – Reviewed and updated  
11/26/12 – Reviewed and updated  
12/01/12 – Reviewed and updated (RxAuth)  
01/09/13 – Reviewed and updated (Onmel® plan exclusion; 12/31/12 file)  
11/25/13 – Reviewed  
11/24/14 – Reviewed and updated  
11/23/15 – Reviewed in P&T Meeting



11/26/18 – Reviewed and updated in P&T Meeting

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