
Prior Authorization DRUG Guidelines

SPORANOX capsules (itraconazole): ANTI/FUNGAL

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Description

Itraconazole is a synthetic triazole antifungal agent used for the treatment of systemic fungal infections in immunocompromised and nonimmunocompromised patients.¹ It is available for oral administration in 100-mg capsules and 10 mg/mL solution. The capsules are approved by the Food and Drug Administration (FDA) for the treatment of blastomycosis (pulmonary and extrapulmonary), histoplasmosis (including chronic cavitary pulmonary disease and disseminated nonmeningeal histoplasmosis), and for aspergillosis (pulmonary and extrapulmonary) in patients who are intolerant of, or refractory to, amphotericin B therapy.¹ Itraconazole oral solution is FDA-indicated for the treatment of oropharyngeal and/or esophageal candidiasis.² This policy does not address the use of itraconazole oral solution.

Recommended Authorization Criteria

Coverage of itraconazole capsules are recommended for those who meet one of the following criteria.

FDA-Approved Indications

1. **Blastomycosis, pulmonary and extrapulmonary.** Approve. Itraconazole is FDA-approved for this condition.¹
2. **Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis.** Approve. Itraconazole is FDA-approved for this condition.¹
3. **Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.** Approve. Itraconazole is FDA-approved for this condition.¹
4. **Onychomycosis (refer to the *Antifungal Therapy for Onychomycosis Therapeutic Guideline* for specific criteria).** Itraconazole is FDA-approved for onychomycosis

of the fingernail and toenail (with or without fingernail involvement) due to dermatophytes (tinea unguium) in non-immunocompromised patients.¹

Other Uses with Supportive Evidence

5. **Tinea corporis.** Approve after a trial of a topical antifungal agent, except for extensive conditions. Itraconazole has been successfully utilized in many trials involving the treatment of tinea corporis;³⁻⁹ however, many topical antifungal agents are similarly effective and are FDA-approved for this condition.²⁰ Systemic therapy may be required for effectiveness or more feasible in extensive conditions.
6. **Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic type).**
Approve after trial of a topical antifungal agent. Itraconazole has been studied and shown to be effective in these tinea-related conditions;³⁻¹⁹ however, many topical antifungal therapies are effective and FDA-approved for these conditions.²⁰⁻²²
7. **Plantar- or moccasin-type dry tinea pedis.** Approve. Oral antifungal therapy is often required for plantar or moccasin-type tinea pedis as topical antifungal agents have led to poor responses or frequent relapses.²³ Studies with itraconazole have shown good results in the treatment of plantar/moccasin-type tinea pedis.²⁴⁻²⁶
8. **Tinea or pityriasis versicolor.** Approve after trial of a topical antifungal agent, except for extensive conditions. Itraconazole has been found efficacious in studies for the treatment and prevention of tinea (pityriasis) versicolor.²⁷⁻³¹ However, many topical agents are FDA-approved and effective for this condition as well.³² Oral therapies, such as itraconazole, are preferred when the disease is widespread.
9. **Tinea capitis.** Approve. Itraconazole has been studied in the treatment of tinea capitis and has been found to be effective.³⁶⁻⁴⁵
10. **Tinea barbae.** Approve. Itraconazole has been reported as effective in case reports involving the treatment of tinea barbae.⁴⁹⁻⁵¹
11. **Treatment of vaginal candidiasis.** Approve after a trial of oral fluconazole. Itraconazole has been effective for the treatment of acute vaginal candidiasis in several studies;⁵²⁻⁵⁹ however, fluconazole and many topical vaginal antifungals are FDA-approved for this condition, effective, and recommended in the 2006 CDC guidelines for the treatment of STDs in reference to VVC.⁶⁰ A recent review article recognizes that itraconazole has been used for vulvovaginal candidiasis
12. **Prevention of recurrent vulvovaginal or vaginal candidiasis.** Approve. Studies have shown itraconazole to be used successfully in the prophylaxis of recurrent vaginal or vulvovaginal candidiasis.⁶¹⁻⁶³ The CDC 2006 treatment guidelines for STDs mention itraconazole as a maintenance regimen, dosed as 400 mg once monthly or 100 mg dosed once daily, for recurrent VVC.⁶¹
13. **Treatment or prevention of other superficial, systemic or suspected fungal infections.** Approve. Itraconazole capsules are well studied in a variety of other systemic and superficial infections.⁶⁴⁻⁷⁷
14. **Patient has been started and stabilized on IV itraconazole therapy or oral itraconazole for a systemic infection and it is being used as continuation therapy.**
Approve. Itraconazole is available as IV therapy and once clinical stabilization has occurred some patients are appropriate candidates for oral therapy.

Exclusions

Coverage of itraconazole capsules is not recommended in the following circumstances:

1. **Candidiasis hypersensitivity syndrome.** The efficacy of itraconazole has not been proved for the cure of this diagnosis.⁷⁸⁻⁷⁹
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

	Sporanox <i>itraconazole</i>
A. Onychomycosis	
1. One of the following: ☐ Member has diabetes OR, ☐ Member has an iatrogenically-induced or disease- associated immunosuppression, such as that due to AIDS, antirejection treatment for bone marrow or solid organ transplant, or chemotherapy for cancer OR, ☐ Member has a systemic dermatosis with impaired skin integrity (e.g., pemphigus, ichthyosis) OR, ☐ Member has a significant vascular compromise (peripheral)	X
2. One of the following: ☐ Contraindication to terbinafine (Lamisil®) OR, ☐ Intolerance to terbinafine (Lamisil) OR, ☐ Failure of an adequate trial of 6 weeks of terbinafine (Lamisil) OR, ☐ Presence of hepatic dysfunction or increased risk for liver disease OR, ☐ Fungal culture indicating lack of sensitivity to terbinafine (Lamisil) OR, ☐ Non-dermatophyte fungal infection (mixed infection, a mold or yeast infection) AND	X
3. One of the following: ☐ Contraindication to itraconazole (Sporanox®) OR, ☐ Intolerance to itraconazole (Sporanox) OR, ☐ Failure of an adequate trial of 6 weeks of itraconazole (Sporanox)	
For onychomycosis, new courses of therapy should not be initiated until 32 weeks following the end of therapy unless infection is noted in a previously unaffected nail (since cure rate continues to increase through the 11th month following initiation of a 12 week course of therapy).	

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2. Sporanox oral solution [package insert]. Toronto, Ontario: Jansen-Ortho Inc.; May 13, 2010.
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