



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Itraconazole

**Brand Name:** Sporanox

**Medication Class:** antifungal

**FDA Approved Uses:** onychomycosis of the toenail and fingernail due to dermatophytes

**Usual Doses:** Toenail onychomycosis-200 mg once daily  
Fingernail onychomycosis- 2 treatment pulses of 200 mg twice daily for  
1 week separated by 3 weeks.

**Duration of Therapy:** Toenail onychomycosis -12 weeks  
Fingernail onychomycosis – 5 weeks (2 treatment pulses for 1 week separated by 3 weeks)

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Patient has an invasive, systemic fungal infection
- Or
- Patient has clinically documented onychomycosis of the finger nails
- Or
- Patient has clinically documented onychomycosis of the toe nails and:
  - is diabetic or immunosuppressed/immunocompromised
  - Or
  - patient is in acute pain due to the onychomycosis with signs of associated soft tissue inflammation
- Or
- For dermal fungal infections (not including onychomycosis) where topical antifungal agents are considered first line therapy:
  - Patient must have failed/intolerant to Rx topical antifungal agent used for an appropriate length of time
  - Or
  - Patient has a chronic, recalcitrant infection
  - Or
  - Patient is immunocompromised

**Contraindications:**

- Congestive heart failure
- Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, tirazolam, lovastatin, and simvastatin.



**Not approved if:**

- Patient does not have a clinically documented fungal infection
- Patient has any contraindications of the use of itraconazole.
- Patient does not meet the above criteria

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_  
Rev. Jul 2005