



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 both an OTC and Rx topical antifungal agent used for an appropriate length of time

Or

 - Patient has an extensive infection involving areas too large to reasonably use a topical agent

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