

ITRACONAZOLE UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Antifungals
Brand (generic) NAME:	Itraconazole (Sporanox) 100 mg capsules GCN 49101 Itraconazole (Hyphanox) 200 mg tablets
PRIOR APPROVAL CRITERIA:	
Itraconazole is considered medically necessary in the following situations:	
1. Treatment of onychomycosis of the toenail or fingernail in patients who meet at least one of the following criteria:	
<ol style="list-style-type: none"> a. Patient is considered immunocompromised (e.g., diabetes, organ transplants, cancer, HIV+) b. Patient has peripheral vascular disease c. Patient has peripheral neuropathy d. Patient has extensive nail involvement that causes significant pain, debilitation and/or paronychia. (MEDICAL RECORD DOCUMENTATION REQUIRED) e. <u>In addition to the above criteria</u>, the onychomycosis diagnosis must be diagnostically confirmed by KOH preparation, fungal culture, nail biopsy, or other assessment documented in the medical record. 	
Benefit approval: 3 months (require 6-month waiting period between treatments)	
2. Treatment of Tinea infection in patients who meet at least one of the following criteria:	
<ol style="list-style-type: none"> a. Tinea capitis or multicentric Tinea corporis diagnostically confirmed by KOH preparation or fungal culture b. Tinea versicolor or other tinea infection not responsive to topical antifungal therapy 	
Benefit approval: 3 months	
3. Treatment of systemic fungal infections: blastomycosis, histoplasmosis, aspergillosis, sporotrichosis, and paracoccidioidomycosis (South American blastomycosis)	
(MEDICAL DOCUMENTATION DOCUMENTATION REQUIRED)	
Benefit approval: 12 months	
BLACK BOX WARNINGS:	
<ul style="list-style-type: none"> • Itraconazole should not be administered for the treatment of onychomycosis in patients with ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration of itraconazole, discontinue administration. • Drug Interactions: Coadministration of cisapride, pimozide, oral midazolam, triazolam, quinidine, dofetilide, nisoldipine, ergot alkaloids, lovastatin, and simvastatin with itraconazole is contraindicated. 	

RATIONALE:

In the majority of cases, a diagnosis of onychomycosis will not present a clinically significant health risk and treatment is often considered cosmetic.

Past Public Health Advisory and product labeling changes for itraconazole encourage more selective prescribing of this drug.

OTHER INFORMATION:

Itraconazole has been associated with serious hepatic toxicity, including liver failure and death, in patients with and without pre-existing liver disease.

Given the possible risks associated with both drugs, product labeling recommends that a diagnosis of onychomycosis be confirmed by laboratory testing (KOH preparation, fungal culture, or nail biopsy) prior to initiating treatment.

REFERENCES:

Sporanox product information. Ortho-McNeil-Janssen Pharmaceuticals. March 2009.

FDA Public Health Advisory. The safety of Sporanox capsules and Lamisil tablets for the treatment of onychomycosis. May 9, 2001. www.fda.gov/cder/drug/advisory/sporanox-lamisil/advisory.htm.