ANTIFUNGAL UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Antifungals
BRAND (generic) NAME:	Lamisil (terbinafine) [250 mg tablets] GCN 60823
	Sporanox (itraconazole) [100 mg capsules] GCN 49101

PRIOR APPROVAL CRITERIA:

Lamisil and/or Sporanox are 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:
   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. **In addition to the above criteria,** 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:
   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 RECORD DOCUMENTATION REQUIRED)**

   Benefit approval: 12 months

BLACK BOX WARNINGS:

Sporanox (itraconazole) should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration of Sporanox, discontinue administration.

Sporanox Drug Interactions: Coadministration of Propulsid (cisapride), Orap (pimozide), oral midazolam, triazolam (Halcion), quinidine, Tikosyn (dofetilide), lovastatin (Mevacor), and simvastatin (Zocor) with Sporanox 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.
- A recent FDA Public Health Advisory and product labeling changes for Sporanox and Lamisil encourage more selective prescribing of antifungals.

OTHER INFORMATION:

Both Sporanox and Lamisil have 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, new product labeling recommends that a diagnosis of onychomycosis be confirmed by laboratory testing (KOH preparation, fungal culture, or nail biopsy) prior to initiating treatment.

Cisapride, oral midazolam, triazolam, pimozide, quinidine, dofetilide, lovastatin and simvastatin (drugs metabolized by CYP3A4) are contraindicated with Sporanox.

Consult package inserts for further information regarding possible drug interactions.

Lamisil is rated Pregnancy Category B. Sporanox is rated Pregnancy Category C.

REFERENCES:

1. Sporanox product information. Janssen Pharmaceutica Products, L.P. April 2001.
2. Lamisil product information. Novartis Pharmaceuticals Corporation. April 2001.
3. 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.
4. The Sanford Guide to Antimicrobial Therapy 2001. Antimicrobial Therapy, Inc. P.O. Box 70, 229 Main Street, Hyde Park, VT 05655, USA.