ITRACONAZOLE

UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Antifungals

**Brand (generic) NAME:**
- Itraconazole (Sporanox) 100 mg capsules
- Itraconazole (Onmel) 200mg 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:
   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 DOCUMENTATION DOCUMENTATION REQUIRED)**

   Benefit approval: 12 months

**BLACK BOX WARNINGS:**

- 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:
