blue of california

itraconazole capsule (SPORANOX)
itraconazole oral solution (SPORANOX)
SPORANOX

Diagnoses Considered for Coverage:

- System fungal infections with Aspergillosis, Blastomycosis, or Histoplasmosis *(for capsule)*
- Onychomycosis *(for capsule)*
- Esophageal or oropharyngeal candidiasis *(for oral solution)*

Coverage Criteria:

For generic itraconazole capsule:

1. **For treatment of systemic fungal infection, approve if:**
    - Culture positive evidence of Aspergillosis, Blastomycosis, Cryptococcosis, Histoplasmosis, or Sporotrichosis, **and**
    - Dose does not exceed FDA label maximum.

2. **For treatment of onychomycosis, approve if:**

Initial Treatment

• Dose does not exceed FDA approved daily or pulse therapy, **and**
• One of the following:
  • Inadequate response, intolerable side effect, or contraindication with oral terbinafine, **or**
  • Positive culture evidence for nail *Candida* is provided.

Reauthorization
• Patient completed a course of antifungal therapy for onychomycosis more than 3 months ago **and** • Dosing does not exceed FDA approved daily or pulse therapy.

For generic itraconazole oral solution:

1. **For treatment of esophageal or oropharyngeal candidiasis, approve if:**
    - Inadequate response, intolerable side effect, or contraindication with fluconazole solution, **and**
    - Dose does not exceed FDA label maximum.

For Closed/Standard plan and request for brand name Sporanox, approve if:

- Meets above criteria for generic, **and**

• Patient has a side effect (intolerance) or allergy to generic that is not expected with the brand.
Coverage Duration: • Active Blastomycosis, Histoplasmosis: up to 12 months • Aspergillosis: 3 months • Onychomycosis: 3 months • Esophageal candidiasis: up to 21 days • Oropharyngeal candidiasis: up to 14 days

Effective Date: 09/27/2023