

***Title: itraconazole (Sporanox)***

<b>Origination:</b> 12/20/02	<b>Revised:</b> 05/25/11	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Definitions***

- **Onychomycosis:** A fungus infection of the nails, causing thickening, roughness and splitting, usually caused by *Trichophyton rubrum* or *T. mentagrophytes*<sup>1</sup>
- **Lunula:** The pale arched area at the proximal portion of the nail plate<sup>1</sup>

***Medication Summaries***

- Sporanox (itraconazole) is indicated for the treatment of onychomycosis of the toenail or fingernail as well as for the treatment of the following fungal infections in immunocompromised and non-immunocompromised Members<sup>3</sup>:

Blastomycosis	Histoplasmosis	Aspergillosis
Candidiasis	Sporotrichosis	Paracoccidioidomycosis

***Eligibility Criteria***

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

***Exclusion Criteria***

- Treatment of onychomycosis is considered to be cosmetic in immunocompetent persons;
- Members with any of the following conditions: ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF; elevated liver function tests (ALT >70 IU/L, AST >96 IU/L, bilirubin total >1.2 mg/dL, bilirubin direct >0.3 mg/dL); history of jaundice or hepatitis; severe neutropenia (ANC<1000);
- Coadministration with other medications metabolized by CYP3A4 specifically cisapride, pimozide, quinidine, dofetilide, or levacetylmethadol (levomethadyl), lovastatin, simvastatin, ergot alkaloids & nisoldipine;
- Members who are pregnant;
- Contraindicated in individuals with hypersensitivity to itraconazole or other azole derivatives.

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**Background Information, continued:**

***Reference Statement***

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

**Procedure:**

- 1.0 Request for itraconazole (Sporanox) for initial therapy for **onychomycosis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
  - 1.1 Member must have a diagnosis of onychomycosis of the toenail and/or fingernail. The presence of dermatophytes must be verified by one (1) of the following:<sup>5</sup>
    - 1.1.1 KOH (potassium hydroxide) smear (or wet mount); **OR**
    - 1.1.1 DTM (Dermatophyte Test Medium); **OR**
    - 1.1.1 Fungal culture;
  - 1.2 Member must be at risk for a systemic fungal infection if the onychomycosis is untreated. Medical documentation verifying a condition that may place a Member at risk must be provided. Conditions that may place a Member at risk, include but are not limited to, the following:
    - 1.2.1 Immunosuppression – as identified by any of the following:
      - 1.2.1.1 Diabetes Mellitis; **OR**
      - 1.2.1.1 Concurrent cancer chemotherapy; **OR**
      - 1.2.1.1 Concurrent chronic oral corticosteroid use; **OR**
      - 1.2.1.1 History of solid organ transplant; **OR**
      - 1.2.1.1 HIV; **OR**
    - 1.2.2 Severe peripheral vascular disease;
  - 1.3 If the Member meets criteria, may approve itraconazole (Sporanox) for 12 weeks.

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**Procedure, continued:**

- 2.0 Request for itraconazole (Sporanox) for a **topical fungal infection other than onychomycosis** requires medical documentation that verifies Member has failed an adequate trial of topical antifungal therapy:<sup>2</sup>
  - 2.1 If the Member meets criterion, may approve for two (2) weeks or for the prescribed course, whichever is less.
- 3.0 Request for itraconazole (Sporanox) for a **systemic fungal infection** requires medical documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
  - 3.1 Member must have a systemic fungal infection including, but not limited to, one (1) of the following:
    - 3.1.1 Blastomycosis; **OR**
    - 3.1.1 Histoplasmosis; **OR**
    - 3.1.1 Aspergillosis; **OR**
    - 3.1.1 Candidiasis; **OR**
    - 3.1.1 Sporotrichosis; **OR**
    - 3.1.1 Paracoccidioidomycosis;
  - 3.2 If the Member meets criterion, may approve for one (1) year or for the prescribed course, whichever is less.

**References:**

1. FDA/Center for Drug Evaluation and Research. Sporanox and Lamisil Public Health Advisory. 9 May 2001.
2. Gilbert DN, ed. et al. The Sanford Guide to Antimicrobial Therapy 2002. 32<sup>nd</sup> ed. 2002.
3. "Guidelines of Care for Superficial Mycotic Infections of the Skin: Onychomycosis." American Academy of Dermatology. Journal of the American Academy of Dermatology. 1996; 34:116-21.
4. Sporanox product monograph. Janssen Pharmaceutical, 2004.
5. Clinical Pharmacology online 2010, Gold Standard, 302 Knights Run Ave., Suite 800, Tampa, FL 33602.

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**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.