

**Title:** *posaconazole (Noxafil)*

<b>Origination:</b> 03/13/07	<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:**

***Medication Summary***

- Posaconazole is triazole antifungal agent that blocks the synthesis of ergosterol, a key component of the fungal cell membrane, through enzyme inhibition.
- Posaconazole is indicated for prophylaxis of invasive *Aspergillus* and *Candida* infections in members who are at high risk of developing these infections due to severe immunosuppression, such as hematopoietic stem cell transplant recipients with graft-versus host disease or Members with hematologic malignancies with prolonged neutropenia from chemotherapy.
- Posaconazole is active against dimorphic fungi and *C. neoformans*, some *Zygomycete sp*, and some of the rarer molds.
- Posaconazole is also indicated for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole (Sporanox) and/or fluconazole (Diflucan). Although cross-resistance among azoles may occur, oral posaconazole is a reasonable option for thrush that is refractory to fluconazole.
- Posaconazole is not approved by the FDA as either primary or salvage therapy for invasive fungal infections.
- Posaconazole is currently only available in an oral formulation and needs to be taken with food for adequate absorption.

***Reference Statement***

- Guidelines are 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.

***Eligibility Criteria***

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) 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.

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**Background Information, continued:**

***Exclusions***

- Members less than 13 years of age.
- Members with hypersensitivity to the active substance or to any of the excipients of posaconazole.
- Co-administration with ergot alkaloids.
- Co-administration with substrates of the enzyme CYP3A4 (including, but not limited to: cisapride, pimozide, or quinidine) due to increased risk of QTc prolongation and torsades de pointes.

**Procedure:**

- 1.0 Request for *initial therapy* requires documentation from the Member's medical records as maintained by the requesting provider verifying the following:
  - 1.1 Member has diagnosis of oropharyngeal candidiasis; **AND**
  - 1.2 Member has tried and failed at least two weeks of therapy with or is not a candidate for fluconazole (Diflucan) or itraconazole (Sporanox);  
**OR**
  - 1.1 Prophylactic use against *Aspergillus* and *Candida* infection; **AND**
    - 1.1.1 Member is immunosuppressed due to:
      - 1.1.1.1 Hematopoietic stem cell transplant secondary to graft-versus host disease; **OR**
      - 1.1.1.1 Hematologic malignancy with prolonged neutropenia secondary to chemotherapy.
- 2.0 If criteria are met, request may be approved up to a maximum dose of 800mg per day (depending on indication) for up to six (6) months.

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**References:**

1. Cornely OA, Maertens J, Winston DJ, et al. Posaconazole vs. fluconazole or itraconazole prophylaxis in patients with neutropenia. N Engl J Med. 2007 Jan 25;356(4):348-59.
2. NCCN Practice Guidelines in Oncology: v.1.2008. Prevention and Treatment of Cancer-Related Infections. 2008 Jan 16; 1-103.
3. Noxafil (Posaconazole) Prescribing Information. Schering Corporation. Kenilworth, NJ. Revised February 2009.
4. Clinical Pharmacology Online. 2009. <http://cpip.gsm.com/>

**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.