

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**NOXAFIL (all dosage forms)**  
**(posaconazole)**

**Status:** CVS Caremark® Criteria

**Type:** Initial Prior Authorization

## POLICY

### FDA-APPROVED INDICATIONS

#### Treatment of Invasive Aspergillosis

**Noxafil injection** and **Noxafil delayed-release tablets** are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

#### Prophylaxis of Invasive Aspergillus and Candida Infections

Noxafil is indicated for the prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- **Noxafil Injection:** adults and pediatric patients 2 years of age and older
- **Noxafil delayed-release tablets:** adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- **Noxafil oral suspension:** adults and pediatric patients 13 years of age and older
- **Noxafil PowderMix for delayed-release oral suspension:** pediatric patients 2 years of age and older who weigh 40 kg or less

#### Treatment of Oropharyngeal Candidiasis Including Oropharyngeal Candidiasis Refractory to Itraconazole and/or Fluconazole

**Noxafil oral suspension** is indicated for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

## COVERAGE CRITERIA

### **Oropharyngeal Candidiasis**

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe oropharyngeal candidiasis when ALL of the following criteria are met:

- The request is for Noxafil oral suspension (immediate-release)
- The patient has experienced an inadequate treatment response, intolerance or has a contraindication to fluconazole AND itraconazole oral solution

### **Prevention of Invasive Aspergillus and Candida Infections**

Authorization may be granted when the requested drug is being prescribed for the prevention of invasive aspergillus and candida infections in a patient who is at high risk of developing these infections due to being severely immunocompromised

### **Treatment of Invasive Aspergillus**

Noxafil PA Policy 3094-A UDR 03-2024.docx

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Authorization may be granted when the requested drug is being prescribed for the treatment of invasive aspergillosis when the following criteria is met:

- The request is for Noxafil injection or Noxafil delayed-release tablets

#### **DURATION OF APPROVAL (DOA)**

- 3094-A: DOA:
  - Prevention of invasive Aspergillus and Candida infections: 6 months
  - Treatment of invasive aspergillosis: 3 months
  - Treatment of moderate to severe oropharyngeal candidiasis: 1 month

#### **REFERENCES**

1. Noxafil [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; September 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed January 12, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/12/2024).
4. Pappas P, Kauffman C, Andes D, et al. Clinical Practice Guidelines for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2016;62:1-50.