

# 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**

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

Noxafil PA Policy 3094-A UDR 03-2024

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- 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.