

# 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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the prevention of invasive *Aspergillus* and *Candida* infections in a patient who is at a high risk of developing these infections due to being severely immunocompromised
- OR**
- Noxafil injection or Noxafil delayed-release tablets are being prescribed for the treatment of invasive aspergillosis
- OR**
- Noxafil oral suspension (immediate-release) is being prescribed for the treatment of moderate to severe oropharyngeal candidiasis
- AND**
- The patient has experienced an inadequate treatment response, intolerance or has a contraindication to fluconazole AND itraconazole oral solution

### REFERENCES

1. Noxafil [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2022.

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed January 24, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed January 18, 2022.
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.