Reference number(s)
3094-A

Initial Prior Authorization
Noxafil

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Noxafil	posaconazole

Indications

FDA-Approved Indications

Treatment of Invasive Aspergillosis

Noxafil is indicated for the treatment of invasive aspergillosis as follows:

- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 to 40 kg

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 who weigh 10 kg or greater
- 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 10 kg to 40 kg

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.

Prophylaxis 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 Aspergillosis

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, Noxafil delayed-release tablets, or Noxafil PowderMix for delayed-release oral suspension.

Reference number(s)
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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; January 2026.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 11, 2025.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/11/2025).
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.