

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 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 the following criteria is met:

- The request is for Noxafil oral suspension (immediate-release)

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:

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

Duration of Approval (DOA)

- 3405-A:
 - 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; October 2024.
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.

Document History

Written by: UM Development (JK)

Date Written: 11/2019 (created REG version of 3094-A 05-2019 removing the trial/failure requirement)

Revised: (ME) 02/2020 (no clinical changes); (NZ) 02/2021 (DOA update), 06/2021 (updated to include newly FDA-approved dosage form Noxafil PowderMix for delayed-release oral suspension); (CJH) 06/2021 (updated q-set to include new indication for treatment of aspergillosis for Noxafil injection and Noxafil delayed-release tabs), (DFW) 02/2022 (no clinical changes), (VLS) 02/2023 (no clinical changes), 02/2024 (no clinical changes), ANB 02/2025 (no clinical changes)

Reviewed: Medical Affairs (CHART) 11/21/2019, (CHART) 02/27/2020, 02/25/2021, 06/17/2021, 07/15/2021, 02/24/2022, 02/23/2023, 02/29/2024, 02/27/2025

External Review: 12/2019 (FYI), 06/2020, 06/2021, 08/2021 (FYI), 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

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|---|--|-----|----|
| 1 | Is the requested drug 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?
[If Yes, then no further questions. If No, then go to 2.] | Yes | No |
| 2 | Which drug is being requested? | | |
| | <input type="checkbox"/> Noxafil Injection (If checked, go to 3) | | |
| | <input type="checkbox"/> Noxafil delayed-release tablets (If checked, go to 3) | | |
| | <input type="checkbox"/> Noxafil oral suspension (immediate-release) (If checked, go to 4) | | |

☐ Noxafil PowderMix for delayed-release oral suspension
(If checked, no further questions)

- | | | | |
|---|---|-----|----|
| 3 | Is the requested drug being prescribed for the treatment of invasive aspergillosis?
[No further questions] | Yes | No |
| 4 | Is the requested drug being prescribed for the treatment of moderate to severe oropharyngeal candidiasis?
[No further questions] | Yes | No |

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Approve, 6 Months	Go to 2	
2.	1=3 ;2=3 ;3=4 ;4=Deny		<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for preventing a certain type of fungal infection when you are at high risk. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis-Noxafil PowderMix]</p>
3.	Approve, 3 Months	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for treatment of a certain type of fungal infection or preventing a certain type of fungal infection when you are at high risk. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p>

			[Short Description: Diagnosis-Noxafil Injection or Noxafil Tablets]
4.	Approve, 1 Months	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for treating a moderate to severe fungal infection of the mouth and throat or preventing a certain type of fungal infection when you are at high risk. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis-Noxafil Oral Solution]</p>