

Posaconazole injection (Noxafil®)

Place of Service
Home Health Administration
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

HCPCS: J3490

NDC: 0085-4331-01

Condition listed in policy (see criteria for details)

- [Invasive *Aspergillus* or *Candida* infection prophylaxis in high-risk patients](#)
- [Treatment of invasive *Aspergillus*](#)

AHFS therapeutic class: Azoles

Mechanism of action: Azole antifungal agent

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for posaconazole injection (Noxafil®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Prophylaxis in high-risk patients: Invasive *Aspergillus* or *Candida* infection

1. Being used for prophylaxis against *Aspergillus* or *Candida* infection, **AND**
2. Being prescribed by or in consultation with an oncologist or infectious disease specialist, **AND**
3. Patient is severely immunocompromised (GVHD, HIV+, chemotherapy-induced neutropenia), **AND**
4. Patient is unable to use oral posaconazole tablet and suspension

Covered dose:

Up to 300 mg IV BID on Day 1, followed by up to 300mg IV once daily thereafter

Coverage period:

Up to 2 months then reassess for continued need for treatment

ICD-10:

Treatment of invasive *Aspergillus*

1. Being used for treatment of culture positive invasive *Aspergillus*, **AND**
2. Patient is unable to use oral posaconazole tablet and suspension

Covered dose:

Up to 300 mg IV BID on Day 1, followed by up to 300mg IV once daily thereafter

Coverage period:

Up to 3 months then reassess for continued need for treatment

ICD-10:

B44.0-B44.2, B44.7, B44.89, B44.9, B48.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for posaconazole injection (Noxafil®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 300 mg per 16.7 mL (18 mg per mL) solution vial

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Noxafil® (Posaconazole injection) [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; 1/2022.
- Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Available at:
https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf
- Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of Candidiasis: 2016 update by the Infectious Disease Society of America. Clin Infect Dis 2016; 62(4):e1-e50.
- Patterson TF, Thompson GR, Denning DW, et al: Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis 2016; 63(4):e1-e60.
- National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections (Version 3.2022). Available at <http://www.nccn.org>.
- Taplitz RA, Kennedy EB, Bow EJ et al. Antimicrobial prophylaxis for adult patients with cancer-related immunosuppression: ASCO and IDSA clinical practice guideline update. J Clin Oncol 2018; 36:3043-3054

(7) Policy Update

Date of initial review: 2Q2022

Date of next review: 2Q2023

Changes from previous policy version:

- New policy

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*