

Noxafil (posaconazole)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|----------------------------------|
| Noxafil (posaconazole) 100 mg | May be subject to quantity limit |
| Noxafil (posaconazole) 40 mg/mL oral suspension | |
| Noxafil (posaconazole) 300mg oral packet | |

APPROVAL CRITERIA

Requests for all dosage forms (oral tables, suspension, or packets) of Noxafil (posaconazole) may be approved when the following criteria are met:

- I. Individual is severely immunocompromised and using for prophylaxis of invasive aspergillus and *Candida* infections, including individuals who are hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies and prolonged chemotherapy-associated neutropenia; **OR**
- II. Individual is using to treat esophageal candidiasis refractory to oral itraconazole and/or fluconazole (AHFS); **OR**
- III. Individual is using to treat invasive aspergillosis; **OR**
- IV. Individual is using as treatment of histoplasmosis and is refractory to or intolerant of oral itraconazole (AHFS); **OR**
- V. Individual is using as salvage therapy for the treatment of mucormycosis when other antifungals are ineffective or cannot be used (AHFS, ESCMID/ECMM 2013); **OR**
- VI. Individual is using to treat oropharyngeal candidiasis including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole; **OR**
- VII. Individual has a diagnosis of human immunodeficiency virus (HIV) infection and is using as treatment or suppressive therapy of coccidioidomycosis that has not responded to fluconazole or itraconazole (AHFS); **OR**
- VIII. Individual is using as salvage therapy for the treatment of infections caused by *Fusarium* and is refractory to or intolerant of primary antifungal therapy (AHFS); **OR**
- IX. Individual is transitioning from inpatient treatment to an outpatient setting and requires continued therapy for an organism susceptible to Noxafil.

Noxafil (posaconazole) may not be approved for the following:

- I. Individual is requesting Noxafil PowderMix and has a known or suspected hereditary fructose intolerance (HFI).

Key References:

1. Centers for Disease Control and Prevention (CDC). Fungal Diseases. Mucormycosis. Available at: <https://www.cdc.gov/fungal/diseases/mucormycosis/health-professionals.html>. Last Reviewed: May 27, 2020. Accessed: October 8, 2022.
2. Centers for Disease Control and Prevention (CDC). Sexually Transmitted Infection Treatment Guidelines, 2021. Available at <https://www.cdc.gov/std/treatment-guidelines/toc.htm>. Accessed: October 9, 2022.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 8, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Galgiani JN, Ampel NM, Blair JE, et al. 2016 Infectious Diseases Society of America (IDSA) Clinical Practice Guideline for the Treatment of Coccidioidomycosis. *Clin Infect Dis*. 2016; 63(6):e112-146.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the HIV Medicine Association of the Infectious Disease Society of America (IDSA). Available at <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new>. Accessed: October 9, 2022.
8. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the prevention and treatment of opportunistic infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/whats-new-guidelines>. Accessed: October 9, 2022.
9. Pappas PG, Kauffman CA, Andes D, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016; 62(4):E1-50.
10. 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 (IDSA). *Clin Infect Dis*. 2016. 63(4): e1-e60.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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