

## PRIOR AUTHORIZATION POLICY

**POLICY:** Antifungal – Noxafil® (posaconazole delayed-release tablets [generics] and oral suspension – Merck)

**DATE REVIEWED:** 06/10/2020

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### OVERVIEW

Noxafil, an azole antifungal, is indicated for 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.<sup>1</sup> Noxafil oral suspension is also indicated for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole. Noxafil delayed-release tablets and oral suspension are indicated for use in patients ≥ 13 years of age. The delayed-release tablets and oral suspension should not be used interchangeably.

The duration of Noxafil therapy is varied. In a pivotal study, where Noxafil oral suspension was compared with fluconazole capsules as prophylaxis for the prevention of invasive fungal infections in allogeneic HSCT recipients with GVHD, the mean duration of Noxafil therapy was 80 days.<sup>1</sup>

### Guidelines/Recommendations

The Infectious Diseases Society of America (IDSA) guidelines for aspergillosis (2016) recommend Noxafil for prophylaxis of invasive aspergillosis.<sup>2</sup> The IDSA guidelines for candidiasis (2016) notes Noxafil as one of the drugs of choice for the treatment of fluconazole-refractory oropharyngeal candidiasis.<sup>3</sup> The National Comprehensive Cancer Network (NCCN) Guidelines for the Prevention and Treatment of Cancer-Related Infections (version 2.2020 – June 5, 2020) recommends Noxafil (category 1) for antifungal prophylaxis in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) and neutropenia who are receiving induction or re-induction chemotherapy; voriconazole is a category 2B recommendation.<sup>4</sup> The IDSA notes Noxafil as having high-quality evidence for prophylaxis of candidiasis, whereas voriconazole is noted as having moderate-quality evidence.

### Other Uses

The IDSA guidelines for aspergillosis (2016) list Noxafil as an option for treatment of invasive aspergillosis that is refractory to other antifungal therapies or that has progressed despite treatment.<sup>2</sup> The guidelines for prevention and treatment of opportunistic infections in adults and adolescents with human immunodeficiency virus (HIV) infections (2019) note Noxafil as an option for treatment of patients with coccidioidomycosis.<sup>4</sup> The NCCN Guidelines for Prevention and Treatment of Cancer-Related Infections (version 2.2020 – June 5, 2020) include Noxafil as one of the antifungal therapies for the following: treatment of mouth and esophageal infections (e.g., oral thrush) refractory to fluconazole; invasive fusariosis; *Scedosporium* infections; and maintenance treatment of mucormycosis.<sup>5</sup> Additionally, the NCCN notes Noxafil as one of the antifungal therapies that are recommended for use as prophylaxis against fungal infections in patients with cancer (e.g., patients with AML or MDS; patients with graft-versus-host disease [GVHD]; hematopoietic cell transplant [HCT] recipients). Antifungal prophylaxis should be continued until resolution of neutropenia or GVHD. Noxafil is active against *Candida* and *Aspergillus* species, some *Zygomycetes* species; and against dimorphic fungi.

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### **POLICY STATEMENT**

Prior authorization is recommended for prescription benefit coverage of Noxafil delayed-release tablets and oral suspension.

**Automation:** None.

### **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Noxafil is recommended in those who meet the following criteria:

#### **FDA-Approved Indications**

1. ***Aspergillus* Infections – Prophylaxis.** Approve for 6 months.
2. ***Candida* Infections (Systemic) – Prophylaxis.** Approve for 6 months.
3. **Oropharyngeal candidiasis – Treatment.** Approve for 3 months.

#### **Other Uses with Supportive Evidence**

4. ***Aspergillus* Infections – Treatment.** Approve for 3 months.
5. **Mouth and Esophageal Infections (Refractory to Other Azole Antifungals) – Treatment.** Approve for 3 months.
6. **Mucormycosis – Maintenance.** Approve for 6 months.
7. **Fusariosis, Invasive – Treatment.** Approve for 3 months.
8. ***Scedosporium* infections – Treatment.** Approve for 3 months.
9. **Fungal Infections (Systemic) In Patients with Human Immunodeficiency Virus (HIV) Infections (e.g., Histoplasmosis, Coccidioidomycosis) – Treatment.** Approve for 3 months.
10. **Fungal Infections (Systemic) In Patients At Risk Of Neutropenia – Prophylaxis.** Approve for 6 months.
11. **Fungal Infections (Systemic) That Are Susceptible to Noxafil – Treatment.** Approve for 3 months.
12. **Patients Currently Receiving Intravenous Noxafil or Oral Noxafil (Tablets or Oral Suspension).** Approve for 3 months to complete the course of therapy.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Noxafil has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-

coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

1. Noxafil<sup>®</sup> delayed-release tablets and oral suspension [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.; March 2020.
2. 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.
3. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;62(4):e1-50.
4. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: [http://aidsinfo.nih.gov/content/files/lvguidelines/adult\\_oi.pdf](http://aidsinfo.nih.gov/content/files/lvguidelines/adult_oi.pdf). Accessed on June 5, 2020.
5. The NCCN Prevention and Treatment of Cancer-Related Infections Clinical Practice Guidelines in Oncology (version 2.2020 – June 5, 2020). ©2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 5, 2020.