PRIOR AUTHORIZATION POLICY

POLICY: Antifungals – Voriconazole tablets and oral suspension (Vfend® – Roerig, a division of Pfizer; generics)

DATE REVIEWED: 06/10/2020

OVERVIEW

Voriconazole (Vfend, generics), an azole antifungal, is indicated in adults and pediatric patients (≥ 2 years of age) for the treatment of invasive aspergillosis, esophageal candidiasis, and for the treatment of serious fungal infections caused by *Scedosporium apiospermum* (asexual form of *Pseudallescheria boydii*) and *Fusarium* spp., including *Fusarium solani* in patients intolerant of, or refractory to, other therapy.[1] Voriconazole is also indicated for the treatment of candidemia in non-neutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds. The duration of voriconazole therapy is varied, ranging from a median duration of 15 days for esophageal candidiasis to 76 days for invasive aspergillosis.

Guidelines/Recommendations

The Infectious Diseases Society of America (IDSA) recommends Voriconazole as a treatment option for invasive aspergillosis (2016) and different invasive syndromes of *Aspergillus* (e.g., invasive pulmonary aspergillosis, invasive sinus aspergillosis, aspergillosis of the central nervous system) and for candidemia and candidiasis (2016).[2,3] The National Comprehensive Cancer Network (NCCN) Guidelines for Prevention and Treatment of Cancer-Related Infections (version 2.2020 – June 5, 2020) note Voriconazole as an option for the treatment of infections caused by *Fusarium* and *Scedosporium* species.[4]

Other Uses

The IDSA guidelines for aspergillosis (2016) recommend Voriconazole for prophylaxis of invasive aspergillosis. The IDSA guidelines for management of candidiasis (2016) note voriconazole as a treatment option for the following infections: *Candida* intravascular infections, including endocarditis and infections of implantable cardiac devices; fluconazole-refractory oropharyngeal candidiasis; *Candida* endophthalmitis.[3] The IDSA guidelines for the management of blastomycosis (2008) note Voriconazole as an option for the treatment of central nervous system blastomycosis.[5] The NCCN Guidelines for Prevention and Treatment of Cancer-Related Infections (version 2.2020 – June 5, 2020) note Voriconazole as an option for prophylactic use against fungal infections in patients at risk of neutropenia (e.g., patients with cancer; patients with graft-versus-host disease [GVHD]; hematopoietic cell transplant [HCT] recipients).[4] Antifungal prophylaxis should be continued until resolution of neutropenia or GVHD; in one study involving HCT recipients, Voriconazole was used for up to 6 months. The guidelines for prevention and treatment of opportunistic infections in adults and adolescents with human immunodeficiency virus (HIV) infections (2019) recommend voriconazole for prophylaxis or chronic suppressive/maintenance treatment for various fungal infections in patients with HIV (e.g., histoplasmosis, coccidioidomycosis, infections caused by *Talaromyces marneffei* [formerly known as *Penicillium marneffei]*).[6]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Vfend tablets and oral suspension and generic voriconazole tablets and oral suspension.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Voriconazole is recommended in those who meet the following criteria:

FDA-Approved Indications

1. ***Aspergillus* Infections – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

2. **Esophageal Candidiasis – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

3. **Infections caused by *Scedosporium apiospermum* – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

4. **Infections caused by *Fusarium* species – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

5. ***Candida* (Systemic) Infections – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):

A) Generic voriconazole tablets or oral suspension is requested; OR
B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

Other Uses with Supportive Evidence

6. ***Aspergillus* Infections – Prophylaxis.** Approve for 6 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

7. **Oropharyngeal Candidiasis (fluconazole-refractory) – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

8. ***Candidia* endophthalmitis – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

9. **Blastomycosis – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
   A) Generic voriconazole tablets or oral suspension is requested; OR
   B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

10. **Fungal Infections (Systemic) in Patients At Risk Of Neutropenia – Prophylaxis.** Approve for 6 months if the patient meets one of the following criteria (A or B):
    A) Generic voriconazole tablets or oral suspension is requested; OR
    B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

11. **Fungal Infections (Systemic) In Patients with Human Immunodeficiency Virus (HIV) – Prophylaxis or Treatment.** Approve for 6 months if the patient meets one of the following criteria (A or B):
    A) Generic voriconazole tablets or oral suspension is requested; OR
    B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

12. **Fungal Infections (Systemic) That Are Susceptible to Voriconazole – Treatment.** Approve for 3 months if the patient meets one of the following criteria (A or B):
    A) Generic voriconazole tablets or oral suspension is requested; OR
    B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

13. **Patients Currently Receiving Intravenous Voriconazole or Oral Voriconazole (Tablets or Oral Suspension).** Approve for 3 months to complete the course of therapy if the patient meets ONE of the following criteria (A or B):
    A) Generic voriconazole tablets or oral suspension is requested; OR
    B) If brand Vfend tablet or brand Vfend oral suspension is requested, the patient has tried the corresponding generic voriconazole product (tablet or oral suspension) AND cannot take the generic voriconazole product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which per the prescribing physician, would result in a significant allergy or serious adverse reaction.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Voriconazole 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. Vfend® tablet and oral suspension [prescribing information]. New York, NY: Roerig, Division of Pfizer; January 2019.
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. 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.
5. Chapman SW, Dismukes WE, Proia LA, et al. Clinical practice guidelines for the management of blastomycosis: 2008 update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2008;46:1801-1812.
6. 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/contentfiles/lvguidelines/adult_oi.pdf. Accessed on June 5, 2020.