PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

VFEND (voriconazole)

Status: CVS Caremark Criteria Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Invasive Aspergillosis

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were *Aspergillus fumigatus*. There was a small number of cases of culture-proven disease due to species of *Aspergillus* other than *A. fumigatus*.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in nonneutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis

Vfend is indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis

Vfend is indicated for the treatment of serious fungal infections caused by *Scedosporium apiospermum* (asexual form of *Pseudallescheria boydii*) and *Fusarium spp*. including *Fusarium solani*, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify causative organism(s). Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.

Compendial Uses

Febrile Neutropenia, Empiric Antifungal Therapy, High-Risk Patients^{2,3,6,8} Invasive Aspergillosis, Prophylaxis, High-Risk Patients^{3,6} Mycosis, Due to *Scedosporium prolificans*³ Oropharyngeal Candidiasis^{2,3,7} Pulmonary Aspergillosis, Chronic^{3,6}

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

The requested drug is being prescribed for any of the following: A) treatment of invasive aspergillosis (including invasive pulmonary aspergillosis), B) serious fungal infection caused by Scedosporium apiospermum and Fusarium species, C) prophylaxis of invasive aspergillosis in a high-risk patient, D) chronic pulmonary aspergillosis, E) empiric antifungal therapy for febrile neutropenia in a high-risk patient, F) mycosis due to Scedosporium prolificans

OR

Vfend PA Policy 241-A 12-2020.docx

©2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

- The requested drug is being prescribed for any of the following: A) candidemia in a non-neutropenic patient, B) disseminated Candida infection in the skin, C) Candida infection in the abdomen, kidney, bladder wall, or wounds, D) esophageal candidiasis, E) oropharyngeal candidiasis
 AND
- The patient has experienced an inadequate treatment response to an alternative antifungal therapy **OR**
- The patient has experienced an intolerance to an alternative antifungal therapy OR
- The patient has a contraindication that would prohibit a trial of an alternative antifungal therapy **AND**
- The patient will use the requested drug orally or intravenously

REFERENCES

- 1. Vfend [package insert]. New York, NY: Pfizer Inc.; September 2020.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2020.
- 3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2020.
- 4. Centers for Disease Control and Prevention. Fungal Diseases. Available at: https://www.cdc.gov/fungal/diseases/aspergillosis/definition.html. Accessed December 2020.
- 5. Pappas PG, Kauffman CA, 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(4):e1-50.
- Patterson TF, Thompson III GR, Denning DW, et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2016;63(4):e1-60.
- Stevens DL, Bisno AL, Chambers HF, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2014;59(2):e10-52.
- Freifeld AG, Bow EJ, Sepkowitz KA et al. Clinical Practice Guideline for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer: 2010 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases* 5011:52(4):e56-93.