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 non-neutropenic 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[2,3,5]
Pulmonary Aspergillosis, Chronic[3,6]

COVERAGE CRITERIA

Aspergillosis, Febrile Neutropenia, Mycosis, Serious Fungal Infection
Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The requested drug is being prescribed for ANY of the following:
    - Treatment of invasive aspergillosis (including invasive pulmonary aspergillosis)
    - Serious fungal infection caused by Scedosporium apiospermum and Fusarium species
    - Prophylaxis of invasive aspergillosis in a high-risk patient
    - Chronic pulmonary aspergillosis
    - Empiric antifungal therapy for febrile neutropenia in a high-risk patient
    - Mycosis due to Scedosporium prolificans
- The patient will use the requested drug orally or intravenously
- If the request is for voriconazole powder for oral suspension, the patient meets ONE of the following: has difficulty swallowing solid oral dosage forms (e.g., tablets), requires a dose that cannot be obtained using the commercially available tablets

Candida Infection

Authorization may be granted when for the requested drug when ALL of the following criteria is met:

- The requested drug is being prescribed for ANY of the following:
    - Candidemia in a non-neutropenic patient
    - Disseminated Candida infection in the skin
    - Candida infection in the abdomen, kidney, bladder wall, or wounds
    - Esophageal candidiasis
    - Oropharyngeal candidiasis
- The patient meets ONE of the following criteria:
    - The patient has experienced an inadequate treatment response to an alternative antifungal therapy
    - The patient has experienced an intolerance to an alternative antifungal therapy
    - The patient has a contraindication that would prohibit a trial of an alternative antifungal therapy
- The patient will use the requested drug orally or intravenously
- If the request is for voriconazole powder for oral suspension, the patient meets ONE of the following: has difficulty swallowing solid oral dosage forms (e.g., tablets), requires a dose that cannot be obtained using the commercially available tablets

DURATION OF APPROVAL (DOA)

- 241-A: DOA: 6 months

REFERENCES

1. Vfend [package insert]. New York, New York: Roerig, Division of Pfizer Inc.; October 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/10/2023).
4. Centers for Disease Control and Prevention. Fungal Diseases. Available at: https://www.cdc.gov/fungal/diseases/aspergillosis/definition.html. Accessed December 10, 2023.
5. Pappas PG, Kauffman CA, Andes DR, 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.
6. 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. *Clin Infect Dis* 2016;63(4):e1-60.
7. 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. *Clin Infect Dis* 2014;59(2):e10-52.
8. 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. *Clin Infect Dis* 2011:52(4):e56-93.