PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

VFEND
(voriconazole)

Status: CVS Caremark Criteria ***REG***
Type: Initial Prior Authorization ***Ref # 2812-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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[2,3,7]
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) candidemia in a non-neutropenic patient, C) disseminated Candida infection in the skin, D) Candida infection in the abdomen, kidney, bladder wall, or wounds, E) esophageal candidiasis, F) serious fungal infections caused by Scedosporium apiospermum and Fusarium species, G) prophylaxis of invasive aspergillosis in a high-risk patient, H) chronic pulmonary aspergillosis, I) empiric antifungal therapy for febrile neutropenia in a high-risk patient, J) oropharyngeal candidiasis, K) mycosis due to Scedosporium prolificans

AND

- The patient will use the requested drug orally or intravenously

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Vfend is indicated for Invasive aspergillosis, Candidemia in non-neutropenic patients, disseminated *Candida* infection in skin and infections in abdomen, kidney, bladder wall, and wounds, Esophageal candidiasis, and 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. Adequate attempts to identify the causative fungal pathogen should be made before therapy is initiated.[1]

According to IDSA guidelines, there are three major forms of aspergillosis: invasive aspergillosis, chronic forms of aspergillosis, and allergic forms of aspergillosis.[6] Invasive aspergillosis most commonly affects the lungs (i.e., invasive pulmonary aspergillosis), but it can also spread to other parts of the body. Chronic pulmonary aspergillosis occurs when Aspergillus infection causes cavities in the lungs and can be a long-term condition (3 months or more).[4]

Vfend has compendia support for use in chronic pulmonary aspergillosis, empiric antifungal therapy for febrile neutropenia in a high-risk patient, oropharyngeal candidiasis, mycosis due to *Scedosporium prolificans*, and prophylaxis of invasive aspergillosis in high-risk patients.[3]

Vfend is only indicated for administration orally or as an intravenous (IV) infusion.[1-3] Coverage will be approved if the prescriber attests the requested drug is being used orally or intravenously.

Duration of treatment with Vfend varies by indication, In general, total duration of therapy for Fusarium and Scedosporium infections should be based on the severity of the patient's underlying disease, recovery from immunosuppression, and response to the drug.[2] In a clinical trial, patients with Scedosporium species infections who had a successful therapeutic response received 28 days or more of Vfend with a median duration of 103 days of treatment.[3] Patients with esophageal candidiasis should be treated for minimum of 14 days and for at least 7 days following resolution of symptoms; per clinical trials, patients were treated with Vfend for a median of 15 days (range 1-49 days).[1-3,5] For candidemia (in non-neutropenic patients) and other deep tissue *Candida* infections, patients should be treated for at least 14 days following resolution of symptoms or following last positive culture, whichever is longer; per clinical trials, the median duration of therapy was 15 days (range 1 to 57 days).[1] For Aspergillosis, the total duration of IV and oral therapy should be based on the severity of the patient's underlying disease, recovery from immunosuppression and response to the drug. In a clinical study in patients with invasive aspergillosis, the median duration of initial IV therapy was 10 days (range 2 to 90 days) and the median duration of maintenance oral therapy was 76 days (range 2 to 232 days). The IDSA recommends that treatment of invasive pulmonary aspergillosis be continued for at least 6 to 12 weeks; patients with Chronic Cavitary Pulmonary Aspergillosis (CCPA) and either pulmonary or general symptoms or progressive loss of lung function or radiographic progression should be treated with a minimum of 6 months of antifungal therapy. [1-3, 6] In order to allow for treatment of complicated infections without a disruption in therapy, coverage will be approved for a duration of 6 months.

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.

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. *Clinical Infectious Diseases* 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. *Clinical Infectious Diseases* 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. *Clinical Infectious Diseases* 5011:52(4):e56-93.

Written by: UM Development (RP)
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for any of the following: A) treatment of invasive aspergillosis (including invasive pulmonary aspergillosis), B) candidemia in a non-neutropenic patient, C) disseminated Candida infection in the skin, D) Candida infection in the abdomen, kidney, bladder wall, or wounds, E) esophageal candidiasis, F) serious fungal infections caused by Scedosporium apiospermum or Fusarium species, G) prophylaxis of invasive aspergillosis in a high-risk patient, H) chronic pulmonary aspergillosis, I) empiric antifungal therapy for febrile neutropenia in a high-risk patient, J) oropharyngeal candidiasis, K) mycosis due to Scedosporium prolificans? [If no, then no further questions.]	Yes	No
2	Will the patient be using the requested drug orally or intravenously?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it for specific types of fungal infections. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
2.	Approve, 6 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are taking it by mouth or as an injection. Your request has been denied based on the information we have. [Short Description: No approvable route of administration]