Reference number(s)
241-A

Initial Prior Authorization
Vfend

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vfend	voriconazole

Indications

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).

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.

Usage

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[2,3,9,11]
- Fungal Peritoneal Dialysis-Associated Peritonitis[3,6]
- Invasive Aspergillosis, Prophylaxis, High-Risk Patients[3,9]
- Mycosis, Due to Scedosporium prolificans[3]
- Oropharyngeal Candidiasis[2,3,8]
- Pulmonary Aspergillosis, Chronic[3,9]
- Talaromycosis[3,5,7]

Coverage Criteria

Aspergillosis, Febrile Neutropenia, Fungal Peritonitis, 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.
  - Fungal Peritoneal Dialysis-Associated Peritonitis.
- 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, Talaromycosis

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:
  - 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.
  - Talaromycosis.
- 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.; August 2024.
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4. Centers for Disease Control and Prevention. Aspergillosis Basics. Available at: https://www.cdc.gov/aspergillosis/about/index.html. Accessed December 11, 2024.
5. Centers for Disease Control and Prevention. Talaromycosis (Penicilliosis) Basics. Available at: https://www.cdc.gov/talaromycosis/about/index.html. Accessed December 11, 2024.
6. Li, Philip Kam-Tao et al. ISPD peritonitis guideline recommendations: 2022 update on prevention and treatment. Peritoneal dialysis international : journal of the International Society for Peritoneal Dialysis vol. 42,2 (2022): 110-153

7. Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. National Institutes of Health, Centers for Disease Control and Prevention, HIV Medicine Association, and Infectious Diseases Society of America. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection. Accessed December 3, 2024.
8. 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.
9. 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.
10. 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.
11. 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.

Document History

Written by: UM Development (SE)

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Revised: (KD/CT) 04/2010 (CAS adapted); (SE) 07/2010; (MS) 08/2011, (SE) 09/2011 (changed duration of approval per CMS PA review); (RP) 08/2012, (CF) 08/2013; (MS) 08/2014, 05/2015; (JH) 05/2016 (no clinical changes), (JG) 04/2017; (RP) 04/2018, 02/2019 (no clinical changes); (KC) 04/2019 (added compendial uses and ROA question), (DFW) 12/2019 (extended DOA, removed MDC designation from title/document), (ME) 12/2020 (no clinical changes); (MRS) 12/2021 (added embedded step for oral suspension); (VLS) 12/2022 (no clinical changes), 12/2023 (no clinical changes); ANB 12/2024 (added talaromycosis and fungal peritonitis as compendial uses)

Reviewed: Medical Affairs (KP) 12/2009, 05/2010, 07/2010, 08/2011, 09/2011, 08/2012, (LS) 08/2013, 08/2014; (DC) 05/2015; (AN) 04/2018; (LMS) 04/2019, (CHART) 01/02/20, (CHART) 12/31/20, (CHART) 12/30/2021, 03/31/2022, 12/29/2022, 12/21/2023, 12/19/2024

External Review: 02/2010, 12/2010, 12/2011, 12/2012, 12/2013, 10/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 04/2020, 04/2021, 04/2022, 04/2023, 04/2024, 04/2025

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) serious	Yes	No

	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, G) fungal peritoneal dialysis-associated peritonitis? [If Yes, then go to 6. If No, then go to 2.]		
2	Is the requested drug 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, F) talaromycosis? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response to an alternative antifungal therapy? [If Yes, then go to 6. If No, then go to 4.]	Yes	No
4	Has the patient experienced an intolerance to an alternative antifungal therapy? [If Yes, then go to 6. If No, then go to 5.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of an alternative antifungal therapy? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Will the patient be using the requested drug orally or intravenously? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Is the request for voriconazole powder for oral suspension? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Does the patient meet ONE of the following: A) has difficulty swallowing solid oral dosage forms (e.g., tablets), B) requires a dose that cannot be obtained using the commercially available tablets? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 6	Go to 2	

2.	Go to 3	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for specific types of fungal infections. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
3.	Go to 6	Go to 4	
4.	Go to 6	Go to 5	
5.	Go to 6	Deny	Your plan only covers this drug if you have tried another antifungal medication, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
6.	Go to 7	Deny	Your plan only covers this drug when you are taking it by mouth or as an injection. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Route of administration]

7.	Go to 8	Approve, 6 Months	
8.	Approve, 6 Months	Deny	Your plan only covers this drug in the dosage form you asked for, oral suspension, when you meet the plan requirements for coverage. There is no medical reason that you are required to take this drug in this dosage form. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Dosage form not approvable]