

Clinical Policy: Voriconazole (Vfend)

Reference Number: AZ.CP.PHAR.39

Effective Date: 11.16.16

Last Review Date: 09.11.18

Line of Business: Arizona Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Voriconazole (Vfend[®]) is an azole antifungal drug.

FDA approved indication

Vfend is indicated for treatment of:

- Invasive aspergillosis
- Serious infections caused by *Scedosporium apiospermum* and *Fusarium spp.*, including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy
- Candidemia (nonneutropenics) and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds
- Esophageal candidiasis

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] that Vfend is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Susceptible Fungal Infections

1. Request meets one of the following:
 - a. Authorization is requested by an infectious disease (ID) specialist physician;
 - b. Discharge from hospital-continuation of therapy;
 - c. Definitive diagnosis of invasive aspergillosis;
 - d. Empiric therapy of aspergillosis in febrile neutropenic transplant patients (usually bone marrow);
 - e. Definitive diagnosis or a strong clinical suspicion of infection caused by *Aspergillus* species, *Fusarium* species or *Scedosporium apiospermum*;
 - f. For candidemia in nonneutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds, and patient must have tried and failed or been intolerant to a course of fluconazole (or caspofungin if *C. glabrata* is suspected) unless culture and sensitivity tests dictate otherwise;
 - g. For esophageal candidiasis, member must have tried and failed or been intolerant to a course of fluconazole;

2. Dose does not exceed 400 mg every 12 hours.

Approval duration: Up to 12 weeks

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Susceptible Fungal Infections(must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Documentation of positive response to therapy [labs, sign/symptom reduction, etc.];
3. If request is for a dose increase, new dose does not exceed 400 mg every 12 hours

Approval duration: Up to 12 weeks

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 or evidence of coverage documents;

- B.** Prophylaxis for fungal infections;

- C.** Patient currently on rifampin, rifabutin, carbamazepine and long-acting barbiturates, sirolimus, terfenadine, astemizole, cisapride, pimozone, quinidine, or ergot alkaloids

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

N/A

Appendix B: General Information

- Definitive diagnosis of invasive aspergillosis depends upon the demonstration of the organism in tissue. In the appropriate clinical setting of pulmonary infiltrates in a patient who is neutropenic or immunosuppressed, visualization of the characteristic fungi is commonly performed using Gomori methenamine silver stain, Calcofluor or a positive culture from sputum, needle biopsy, or bronchoalveolar lavage (BAL) fluid.
- After bone marrow transplantation a positive *Aspergillus* culture from sputum has a 95% positive predictive value for invasive disease.
- Pulmonary or infectious disease consultation in patients suspected of having invasive aspergillosis or chronic necrotizing *Aspergillus* pneumonia may be helpful in obtaining a diagnosis.

- Visual disturbances have been reported in up to 18.7% of study patients. The effect of VFEND is not known if treatment continues after 28 days; if necessary visual monitoring should occur.
- Efficacy and safety studies have not been performed in patients less than 12 years of age.
- Voriconazole can cause fetal harm when administered to fetal women.
- Use half the maintenance dose in patients with **mild to moderate hepatic impairment**
- Avoid IV administration in patients with **moderate to severe renal impairment** (CrCl < 50 mL/min)

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
Treatment of Aspergillosis		
Amphotericin B	Amphotericin: 0.5-1.5 mg/kg/d Abelcet: 5 mg/kg/d Amphotec: 3-4 mg/kg/d; up to 7.5 mg/kg/d may be required in severe illness AmBisome: 3-5 mg/kg/d Inhaled amphotericin for <i>Aspergillus</i> prophylaxis or colonization: 50 mg/d preceded by albuterol	Amphotec: 7.5 mg/kg/d
Sporanox® (itraconazole)	Oral: 200-400 mg/day Administer loading dose for life-threatening infections: 200 mg IV bid x 4 doses or 200 mg po tid for 3 days	Capsules: 400 mg/day Intravenous: Safety & efficacy beyond 14 days is unknown
Treatment of esophageal candidiasis		
Diflucan® (fluconazole)	Esophageal candidiasis: 200 mg Day 1 followed by 100 mg qd for 14-21 days and 2 weeks after resolution of symptoms	400 mg/day
Sporanox (itraconazole)	Oral suspension: 100-200 mg/day on an empty stomach for 2-4 weeks	Limited data beyond 6 months

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen IV	Dosing Regimen PO	Maximum Dose
Invasive Aspergillosis	6 mg/kg q 12 hrs x 24 hrs. Then 4 mg/kg q 12 hrs	200 mg q 12 hrs	Loading: 6 mg/kg x 2 doses Maintenance 4 mg/kg
Candidemia in	6 mg/kg q 12 hrs x 24	200 mg q 12 hrs	Loading: 6 mg/kg

non-neutropenics and other deep tissue <i>Candida</i> infections	hrs. Then 3-4 mg/kg q 12 hrs		x 2 doses Maintenance 4 mg/kg
Scedosporiosis and Fusariosis	6 mg/kg q 12 hrs x 24 hrs. Then 4 mg/kg q 12 hrs	200 mg q 12 hrs	Loading: 6 mg/kg x 2 doses Maintenance 4 mg/kg
Esophageal Candidiasis	Not evaluated	200 mg q 12 hrs	400 mg daily

Adult patients weighing less than 40 kg: PO maintenance dose 100 or 150 mg q 12 hrs

VI. Product Availability

Drug	Availability
Voriconazole	Tablets: 50 and 200 mg
Voriconazole	Suspension: 40 mg/ml
Voriconazole	Injection: 200 mg
Vfend I.V.	Powder for IV Soln: 200 mg
Vfend	Powder for oral suspension: 40 mg
Vfend	Tablets: 50 and 200 mg

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	07.08.17	11.17
Updated references with addition of IDSA treatment guidelines	09.11.18	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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