BlueCross BlueShield
Federal Employee Program.
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.01.044

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	February 23, 2018
Subject:	Vfend	**Page:**	1 of 5

Last Review Date: June 13, 2024

Vfend

Description

Vfend IV injection, tablets, suspension (voriconazole)

Background
Vfend (voriconazole) is a potent “azole” antifungal medication. Azole antifungal medications work by inhibiting fungal ergosterol biosynthesis (ergosterol is a component of fungal cell membranes). Specifically, voriconazole disrupts the specific fungal enzyme which is crucial in making ergosterol, thereby destroying the fungal cell wall. Voriconazole is used in the treatment of fungal infections including: invasive aspergillosis, Candidemia in nonneutropenics and other deep tissue Candida infections, Scedosporiosis and Fusariosis infections, and esophageal candidiasis (1).

Regulatory Status
FDA-approved indications: Vfend is an azole antifungal indicated for use in the treatment of: (1)

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

Off-Label Uses: (2)

1. Use in select (high risk) neutropenic cancer patients for antifungal prophylaxis

Vfend has many warnings and precautions including: clinically significant drug interactions, hepatic toxicity, visual disturbances (especially with extended use), embryo-fetal toxicity, arrhythmias and QT prolongation, infusion related reactions (including anaphylaxis), dermatological reactions, and skeletal events (with long term use). Baseline transaminase levels and bilirubin should be measured at the initiation of Vfend therapy and monitored frequently throughout the duration of therapy (weekly for the first month, and monthly thereafter) (1).

Vfend (voriconazole) comes in three main dosage forms: a film coated tablet, a powder for suspension (oral), and a powder for solution (for IV injection). There is no FDA approved indication for use of this compound in any other form, including topically, or via inhalation (1).

The Infectious Diseases Society of America (IDSA) recommends that serum trough drug levels be obtained for azole antifungal agents such as Vfend (voriconazole) to optimize therapeutic efficacy and to avoid potential toxicity (3).

Safety and effectiveness in patients less than 2 years of age have not been established (1).

Related policies
Ketoconazole, Sporanox-Onmel

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vfend may be considered **medically necessary** if the conditions indicated below are met.

Vfend may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Invasive aspergillosis

2. Candidemia
3. Disseminated candidiasis (in skin, abdomen, kidney, bladder wall, and/or wounds)
4. Esophageal candidiasis
5. Serious infections caused by *Scedosporium apiospermum* and *Fusarium* species
6. Fungal prophylaxis in neutropenic cancer patients

AND ALL of the following:

a. Agreement to monitor LFTs, including transaminases and bilirubin
b. **NOT** for topical use
c. **NOT** for inhalation

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity

Drug	Quantity
Vfend IV injectable	None
Vfend tablets (50 mg and 200 mg tablets)	60 tablets per 365 days **OR**
Vfend oral suspension	225 mL per 365 days

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Vfend (voriconazole) is a potent “azole” antifungal medication. Voriconazole is used in the treatment of fungal infections including: invasive aspergillosis, Candidemia in nonneutropenics and other deep tissue Candida infections, Scedosporiosis and Fusariosis infections, and esophageal candidiasis. Voriconazole is also used off-label as an alternative therapy in the prevention of invasive fungal infections in immunocompromised patients, such as high-risk neutropenic patients with cancer. Vfend (voriconazole) comes in three main dosage forms: a film coated tablet, a powder for suspension (oral), and a powder for solution (for IV injection). There is no FDA approved indication for use of this compound in any other form, including topically, or via inhalation (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vfend while maintaining optimal therapeutic outcomes.

References

1. Vfend [package insert]. New York, NY: Pfizer, Inc.; October 2022.
2. Freifeld AG, Bow EJ, Sepkowitz KA, et al.; Infectious Diseases Society of America. 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).
3. Patterson, T.F., et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Disease Society of America. Clinical Infectious Diseases, Volume 63, Issue 4, 15 August 2016, Pages e1-e60.

Policy History

Date	Action
February 2018	Addition to PA
June 2018	Annual review
February 2019	Reduction of age requirement to 2 years or older
March 2019	Annual review. Addition of serum trough monitoring statement to regulatory status per SME
December 2019	Annual review. Addition of PA quantity limit of 180 units for the Vfend suspension
December 2020	Annual review and reference update
December 2021	Annual review and reference update
October 2022	Revised Pre-PA limit for Vfend suspension to 225 mL due to package sizing. Removed Vfend suspension PA quantity limit due to variation in dosing and duration

December 2022	Annual review
June 2023	Annual review and reference update
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.