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| <b>Section:</b>    | Prescription Drugs    | <b>Effective Date:</b>       | July 1, 2026      |
| <b>Subsection:</b> | Anti-Infective Agents | <b>Original Policy Date:</b> | February 23, 2018 |
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**Last Review Date:** June 11, 2026

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## Vfend

### Description

Vfend IV injection, tablets, suspension (voriconazole)

Vfend tablets (voriconazole)

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### 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

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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).

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## 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:

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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                              |
| Voriconazole* tablets (50 mg and 200 mg tablets) | 60 tablets per 365 days <b>OR</b> |
| Vfend oral suspension                            | 225 mL per 365 days               |

## Prior - Approval Limits

| Drug                  | Duration |
|-----------------------|----------|
| Vfend IV injectable   | 3 months |
| Vfend oral suspension | 3 months |
| Drug with approved FE | Duration |
| Vfend oral suspension | 3 months |

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|                                  |          |
|----------------------------------|----------|
| Vfend <b>brand</b> 50 mg tablets | 3 months |
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### 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.; March 2025.
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 |

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|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                 |
| June 2025     | Annual review and reference update                                                                                                                            |
| December 2025 | Annual review. Per FEP, Vfend brand 50 mg tablets require an approved FE                                                                                      |
| June 2026     | Annual review                                                                                                                                                 |

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.**