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 indication: 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 are 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** for patients 2 years of age or older for the treatment of invasive aspergillosis, candidemia, disseminated candidiasis (deep tissue *Candida* infections), esophageal candidiasis, serious infections caused *Scedosporium apiospermum* and *Fusarium* species, and as fungal prophylaxis is neutropenic cancer patients and if all the conditions indicated below are met.

Vfend may be considered **investigational** in patients less than 2 years of age and 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 *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**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity per 365 days</th>
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<tr>
<td>Vfend IV injectable</td>
<td>None</td>
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<tr>
<td>Vfend tablets (50 mg and 200 mg tablets)</td>
<td>60 tablets per 365 days OR</td>
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<tr>
<td>Vfend oral suspension</td>
<td>200 mL per 365 days</td>
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Prior - Approval Limits

**Quantity**

Vfend oral suspension **only**: 180 mL
Vfend IV and tablets: no limit

**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 are 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**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>February 2018</td>
<td>Addition to PA</td>
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<tr>
<td>June 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>February 2019</td>
<td>Reduction of age requirement to 2 years or older</td>
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<tr>
<td>March 2019</td>
<td>Annual review. Addition of serum trough monitoring statement to regulatory status per SME</td>
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December 2019     Annual review. Addition of PA quantity limit of 180 units for the Vfend suspension

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.