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# 5.01.35

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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2019 |
| **Subsection:** | Anti-infective Agents | **Original Policy Date:** | October 1, 2015 |
| **Subject:** | Cresemba | **Page:** | 1 of 4 |

***Last Review Date:*** November 30, 2018

# Cresemba

## Description

### Cresemba (isavuconazonium)

**Background**
Cresemba belongs to a class of drugs called azole antifungal agents, which target the cell membrane of a fungus. Cresemba is used to treat adults with invasive aspergillosis and invasive mucormycosis. Aspergillosis is a fungal infection caused by Aspergillus species, and mucormycosis is caused by the Mucorales fungi. These infections occur most often in people with weakened immune systems (1).

**Regulatory Status**
FDA-approved indication: Cresemba is an azole antifungal indicated for use in the treatment of invasive aspergillosis and invasive mucormycosis (1).

Cresemba is contraindicated in patients with familial short QT syndrome. Cresemba is also contraindicated when co-administered with strong CYP3A4 inhibitors or strong CYP3A4 inducers (1).

Specimens for fungal culture and other relevant laboratory studies (including histopathology) to isolate and identify causative organism(s) should be obtained prior to initiating antifungal therapy (1).

Hepatic adverse drug reactions (e.g., elevations in alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin) have been reported in clinical trials. Evaluate liver-related laboratory tests at the start and during the course of Cresemba therapy. Monitor patients who develop abnormal liver-related laboratory tests during Cresemba

therapy for the development of more severe hepatic injury. Cresemba has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and should be used in these patients only when the benefits outweigh the risks (1).

The safety and efficacy of Cresemba in patients less than 18 years of age have not been established (1).

**Related policies**
Ketoconazole, Sporanox Onmel, Vfend

## Policy

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

Cresemba may be considered **medically necessary** in patients 18 years of age or older for the use in the treatment of invasive aspergillosis and invasive mucormycosis and if the conditions indicated below are met.

Cresemba may be considered **investigational** in patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following

1. Invasive Aspergillosis
2. Invasive Mucormycosis

**AND ALL** of the following:

1. Laboratory and clinical documentation of causative organism(s)
2. Baseline liver function tests and monitored during the course of treatment with adjustment in dosing dependent on severity of liver function

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following

1. Invasive Aspergillosis
2. Invasive Mucormycosis

**AND ALL** of the following:

1. Liver function tests monitored during the course of treatment with adjustment in dosing dependent on severity of liver function

## Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Cresemba IV**

**Quantity** 94 vials
**Duration** 3 months

**Cresemba Oral**

**Quantity** 188 capsules
**Duration** 3 months

## Prior – Approval *Renewal* Limits

**Cresemba IV**

**Quantity** 90 vials
**Duration** 3 months (One renewal only)

**Cresemba Oral**

**Quantity** 180 capsules
**Duration** 3 months (One renewal only)

## Rationale

**Summary**
Cresemba is used to treat adults with invasive aspergillosis and invasive mucormycosis. Aspergillosis is a fungal infection caused by Aspergillus species, and mucormycosis is caused by the Mucorales fungi. These infections occur most often in people with weakened immune systems. The safety and efficacy of Cresemba in patients less than 18 years of age have not been established (1).

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

**References**

1. Cresemba [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; April 2018.

## Policy History

| Date | Action |
|---|---|
| October 2015 | Addition to PA. |
| March 2016 | Annual editorial review and reference update<br>Policy code changed from 5.03.35 to 5.01.35 |
| December 2017 | Annual editorial review and reference update |
| November 2018 | Annual editorial review and reference update |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on November 30, 2018 and is effective January 1, 2019.**