BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.01.035

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Anti-infective Agents	**Original Policy Date:**	October 1, 2015
Subject:	Cresemba	**Page:**	1 of 5

Last Review Date: March 6, 2026

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 indications: Cresemba is an azole antifungal indicated for use in the treatment of invasive aspergillosis and invasive mucormycosis as follows (1):

- Cresemba for injection: adults and pediatric patients 1 year of age and older
- Cresemba capsules: adults and pediatric patients 6 years of age and older who weigh 16 kilograms (kg) and greater

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 1 year of age have not been established (1).

Related policies
Itraconazole, Ketoconazole, 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** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age

IV injection**:** 1 year of age or older
Injection via nasogastric (NG) tube: 6 years of age or older **AND** weight ≥ 16 kg
Oral capsules: 6 years of age or older **AND** weight ≥ 16 kg

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 IV injection: 1 year of age or older
Injection via nasogastric (NG) tube: 6 years of age or older **AND** weight ≥ 16 kg
Oral capsules: 6 years of age or older **AND** weight ≥ 16 kg

Diagnoses

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

1. Invasive Aspergillosis
2. Invasive Mucormycosis

AND 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

Strength	Quantity
74.5 mg	470 capsules **OR**
186 mg	188 capsules

Duration 3 months

Prior – Approval *Renewal* Limits

Cresemba IV

Quantity 90 vials
Duration 3 months (One renewal only)

Cresemba Oral

Strength	Quantity
74.5 mg	450 capsules **OR**
186 mg	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 1 year 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 2025.

Policy History

Date	Action
October 2015	Addition to PA.
March 2016	Annual editorial review and reference update 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
June 2019	Annual review
December 2020	Annual review and reference update
March 2021	Annual review
December 2021	Annual review and reference update
March 2022	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.01.035
March 2023	Annual review and reference update
June 2023	Annual review
September 2023	Per PI update, addition of 74.5 mg capsule
December 2023	Annual review
January 2024	Per PI update, lowered age requirement for IV injection to 1 year and older and capsules/injection via NG tube to 6 years and older who weigh 16 kg or greater
March 2024	Annual review
June 2024	Annual review
March 2025	Annual review
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.