

Commercial/Healthcare Exchange PA Criteria

Effective: October 1, 2020

Prior Authorization: Cresemba

Products Affected: Cresemba® (isavuconazonium sulfate) oral capsule

Medication Description: Isavuconazonium sulfate is a prodrug that is rapidly hydrolyzed in the blood to active isavuconazole. Isavuconazole inhibits the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of cytochrome P-450 dependent enzyme lanosterol 14-alpha-demethylase. This enzyme is responsible for the conversion of lanosterol to ergosterol. An accumulation of methylated sterol precursors and a depletion of ergosterol within the fungal cell membrane weakens the membrane structure and function.

Covered Uses:

1. Treatment of invasive aspergillosis in patients 18 years of age or older.
2. Treatment of invasive mucormycosis in patients 18 years of age or older.

Exclusion Criteria:

1. Known hypersensitivity to isavuconazole.
2. Coadministration of strong CYP3A4 inhibitors, such as ketoconazole, high-dose ritonavir (400 mg every 12 hours).
3. Coadministration of strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long acting barbiturates.
4. Familial short QT syndrome

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, and infectious disease specialist, transplant physician, hematologist, or oncologist.

Coverage Duration: 3 months

Other Criteria:

Invasive Aspergillosis

- A. Patient has a diagnosis of invasive aspergillosis; **AND**
- B. Patient has had a fungal culture report showing causative organisms are sensitive to isavuconazonium; **AND**
- C. Patient has a documented adequate trial of, or has shown an intolerance to, voriconazole.

Invasive Mucormycosis

- A. Patient has a diagnosis of invasive mucomycosis; **AND**
- B. Patient has had a fungal culture report showing causative organisms are sensitive to isavuconazonium

References:

1. Cresemba (isavuconazonium) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; September 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/1/2020

