isavuconazonium (Cresemba)

Commercial Medical Benefit Drug Policy

Place of Service

Infusion Center Administration
Office Administration
Outpatient Facility Administration
Home Infusion Administration
Hospital Administration

Drug Details

USP Category: ANTIFUNGALS
Mechanism of Action: Isavuconazonium sulfate is a prodrug that is rapidly hydrolyzed in the blood to active isavuconazole.
HCPCS:
J1833:Injection, isavuconazonium, 1 mg
How Supplied:
372 mg of isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Invasive Aspergillosis
- Invasive Mucormycosis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Invasive Aspergillosis
Meets medical necessity if all the following are met:
1. Culture positive for *Aspergillus sp*
2. Medical rationale why voriconazole cannot be used

Covered Doses:
Up to 372 mg given intravenously every 8 hours for 6 doses followed by 372 mg given daily beginning 12 to 24 hours following the 6th dose

Coverage Period:
Up to 3 months and then assess for continued efficacy and patient is unable to switch to oral formulation.

ICD-10:
B44.0-B44.2, B44.7, B44.81, B44.89, B44.9, B48.4

Invasive Mucormycosis

Meets medical necessity if all the following are met:

1. Meets one of the following (a or b):
   a. Culture positive for mucormyocosis pathogens (e.g. *Rhizopus, Rhizomucor, Lichtheimia, Mucormycetes*)
   b. Being prescribed or recommended by an infectious disease specialist

Covered Doses:
Up to 372 mg given intravenously every 8 hours for 6 doses followed by 372 mg given daily beginning 12 to 24 hours following the 6th dose

Coverage Period:
Up to 3 months and then assess for continued efficacy and patient is unable to switch to oral formulation.

ICD-10:
B46.0 - B46.5, B46.8, B46.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Cresemba (isavuconazonium) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; March 2025.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
4. Patterson TF, Thompson GR, Denning DW, et al: Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis 2016; 63(4): e1-e60.
5. Candidiasis (Mucocutaneous). In: US Department of Health and Human Services (HHS) Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf. Updated May 26, 2020. Accessed June 16, 2021.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

Reviewed by P&T Committee