

# Cresemba (isavuconazonium)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cresemba (isavuconazonium) 74.5mg*	5 capsules per day
Cresemba (isavuconazonium) 186mg*	2 capsules per day
Cresemba 372 (isavuconazonium) mg powder for injection*	1 vial per day

\*Loading dose: May approve up to an additional 8 capsules of 186mg, or 20 capsules of 74.5mg, or 4 vials in the first 48 hours of treatment.

## **APPROVAL CRITERIA**

Requests for Cresemba (isavuconazonium) may be approved if the following criteria are met:

- I. Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergillosis or mucormycosis or an organism susceptible to Cresemba in an outpatient setting;

### **OR**

- II. Individual has a diagnosis of invasive aspergillosis; **AND**
- III. Individual has had an inadequate response to, is intolerant of, or has a contraindication to voriconazole or liposomal amphotericin B (Patterson 2016);

### **OR**

- IV. Individual has a diagnosis of invasive mucormycosis; **AND**
- V. Individual has had an inadequate response to is intolerant of, or has a contraindication to amphotericin B (CDC-Mucormycosis);

### **OR**

- VI. Individual has a diagnosis of human immunodeficiency virus (HIV) infection and is using to treat esophageal candidiasis refractory to oral itraconazole and/or fluconazole (AHFS).

Cresemba (isavuconazonium) may not be approved for the following:

- I. Individual has a diagnosis or history of familial short QT syndrome; **OR**
- II. Use in combination with strong CYP3A4 inhibitors (including ketoconazole or high-dose ritonavir); **OR**
- III. Use in combination with strong CYP3A4 inducers (including rifampin, carbamazepine, St. John's wort or long-acting barbiturates).

### **Key References:**

1. Centers for Disease Control and Prevention (CDC). Fungal Diseases. Mucormycosis. Available at: <https://www.cdc.gov/fungal/diseases/mucormycosis/health-professionals.html>. Last Reviewed: May 27, 2020. Accessed: October 8, 2022.
2. Centers for Disease Control and Prevention (CDC). Sexually Transmitted Infection Treatment Guidelines, 2021. Available at <https://www.cdc.gov/std/treatment-guidelines/toc.htm>. Accessed: October 9, 2022.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 8, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. 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 (CDC), the National Institutes of Health (NIH), and the HIV Medicine Association of the Infectious Disease Society of America (IDSA). Available at <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new>. Accessed: October 9, 2022.
7. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the prevention and treatment of opportunistic infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/whats-new-guidelines>. Accessed: October 9, 2022.
8. 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 (IDSA). *Clin Infect Dis*. 2016. 63(4): e1-e60.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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