Isavuconazonium sulfate (Cresemba®)	Place of Service Infusion Center Administration Office Administration Outpatient Facility Administration Home Infusion Administration Hospital Administration HCPCS: J3490

Conditions listed in policy (*see criteria for details*)

- Invasive aspergillosis
- Invasive mucormycosis

AHFS therapeutic class: Azoles
Mechanism of action: Azole antifungal

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Cresemba® (Isavuconazonium sulfate) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Invasive aspergillosis

1. Culture positive for *Aspergillus sp*, **AND**
2. Medical rationale why voriconazole cannot be used

Covered Doses
Up to 372 mg IV q 8 hours x 6 doses followed by 372 mg IV daily beginning 12 to 24 hours following 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

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

Covered Doses
Up to 372 mg IV q 8 hours x 6 doses followed by 372 mg IV daily beginning 12 to 24 hours following 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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Cresemba® (Isavuconazonium sulfate) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
372 mg of isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) single-dose vial as a sterile lyophilized powder

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Cresemba® (isavuconazonium sulfate) [Prescribing information]. Astellas Pharma US, Inc., Northbrook, IL 2/2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Prevention And Treatment of Cancer-Related Infections (Volume 3.2022). Available at: www.nccn.org/
- 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.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.