

PRIOR AUTHORIZATION POLICY

POLICY: Antifungals – Cresemba (Oral) Prior Authorization Policy

- Cresemba® (isavuconazonium sulfate capsules – Astellas Pharma)

REVIEW DATE: 06/23/2021

OVERVIEW

Cresemba, an azole antifungal, is indicated for use in patients ≥ 18 years of age for the treatment of **invasive aspergillosis and invasive mucormycosis**.¹ Cresemba is also available for use as an intravenous (IV) infusion. Switching between the IV and oral formulations is acceptable as the two formulations are bioequivalent.

In the pivotal study involving patients with invasive aspergillosis, patients were initiated on IV Cresemba before transitioning to oral Cresemba therapy.¹ The mean treatment duration was 47 days, of which patients received IV Cresemba for 8 to 9 days. In an open-label, non-comparative study that included a subset of patients with invasive mucormycosis, patients were treated with either IV or oral Cresemba. The median duration of Cresemba therapy was 102 days.

Guidelines/Recommendations

The Infectious Diseases Society of America (IDSA) [2016] recommends Cresemba as a treatment option for invasive aspergillosis and different invasive syndromes of *Aspergillus* (e.g., invasive pulmonary aspergillosis, invasive sinus aspergillosis, aspergillosis of the central nervous system).² Treatment of invasive aspergillosis should be continued for a minimum of 6 to 12 weeks, depending on the degree and duration of immunosuppression, site of disease, and evidence of disease improvement.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cresemba capsules. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cresemba capsules is recommended in those who meet the following criteria:

FDA-Approved Indications

1. ***Aspergillus* Infection – Treatment.** Approve for 3 months.
2. **Mucormycosis – Treatment.** Approve for 3 months.

Other Uses with Supportive Evidence

3. **Fungal Infection (Systemic) That Is Susceptible to Cresemba – Treatment.** Approve for 3 months.

- 4. Patient Currently Receiving Intravenous Cresemba or Oral Cresemba Capsules.** Approve for 3 months to complete the course of therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cresemba capsules is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cresemba[®] capsules [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; May 2021.
2. 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.