

## PRIOR AUTHORIZATION POLICY

**POLICY:** Antifungal – Cresemba® (isavuconazonium sulfate capsules – Astellas Pharma)

**DATE REVIEWED:** 06/10/2020

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### OVERVIEW

Cresemba, an azole antifungal, is indicated for use in patients  $\geq 18$  years of age for the treatment of invasive aspergillosis or invasive mucormycosis.<sup>1</sup> 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.<sup>1</sup> 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, etc).<sup>2</sup> 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.

The European Conference on Infections in Leukemia (ECIL), a collaboration between the European Organization for Research and Treatment of Cancer (EORTC), the European Society for Bone and Marrow Transplantation (EBMT), the European Leukemia Net (ELN), and the International Immunocompromised Host Society (CSH), provided recommendations for the treatment of several types of fungal infections, including invasive aspergillosis and mucormycosis in hematologic patients (2016).<sup>3</sup> The ECIL-6 recommendations list Cresemba, among other antifungals, as first-line for the treatment of invasive aspergillosis (A1 grade; good evidence from at least one properly randomized, controlled trial). The panel recommends a multidisciplinary approach, including antifungal therapy (amphotericin B), surgery, and control of the underlying conditions (e.g., control of diabetes, use of hematopoietic growth factor if the patient is neutropenic, discontinuation/tapering of steroids, reduction of immunosuppressive therapy).

The European Society for Clinical Microbiology and Infectious Diseases (ESCMID) and the European Confederation of Medical Mycology (ECMM) published joint clinical guidelines for the management of mucormycosis in 2013.<sup>4</sup> The panel notes that there are no published, well-designed, randomized clinical efficacy trials in the field of mucormycosis. Surgery, whenever possible, is strongly recommended to be combined with medical treatment. The drug of choice for the treatment of invasive mucormycosis is liposomal amphotericin B.

The National Comprehensive Cancer Network (NCCN) Prevention and Treatment of Cancer-Related Infections clinical guidelines (version 2.2020 – June 5, 2020) note that Cresemba is currently not recommended for use as prophylaxis against fungal infections in patients with cancer and neutropenia.<sup>5</sup>

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## **POLICY STATEMENT**

Prior authorization is recommended for prescription benefit coverage of Cresemba capsules.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

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

### **FDA-Approved Indications**

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

### **Other Uses with Supportive Evidence**

3. **Fungal Infections (Systemic) That Are Susceptible to Cresemba – Treatment.** Approve for 3 months.
4. **Patients Currently Receiving Intravenous Cresemba or Oral Cresemba Capsules.** Approve for 3 months to complete the course of therapy.

## **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Cresemba has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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<sup>®</sup> capsules [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; December 2019.
  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.
  3. Tissot F, Agrawal S, Pagano L, et al. ECIL-6 guidelines for the treatment of invasive candidiasis, aspergillosis, and mucormycosis in leukemia and hematopoietic stem cell transplant patients. *Haematologica.* 2017;102(3):433-444.
  4. Cornely OA, Arikan-Akdagli S, Dannaoui E, et al. ESCMID and ECMM joint clinical guidelines for the diagnosis and management of mucormycosis 2013. *Clin Microbiol Infect.* 2014;20(Suppl 3):5-26.
  5. The NCCN Prevention and Treatment of Cancer-Related Infections Clinical Practice Guidelines in Oncology (version 2.2020 –June 5, 2020). ©2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 5, 2020.
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