PRIOR AUTHORIZATION POLICY

POLICY: Antifungals – Cresemba (Oral) Prior Authorization Policy
- Cresemba® (isavuconazonium sulfate capsules – Astellas Pharma)

REVIEW DATE: 07/31/2024

OVERVIEW

Cresemba, an azole antifungal, is indicated in adults and pediatric patients ≥ 6 years of age who weigh ≥ 16 kg for the following uses:[1]

- **Invasive aspergillosis.**
- **Invasive mucormycosis.**

Cresemba is also available for use as an intravenous (IV) infusion.[1] Switching between the IV and oral formulation is acceptable as the two formulations are bioequivalent. Patients are typically transitioned from the IV formulation to the oral formulation while in the hospital or upon discharge. In the pivotal study involving patients with invasive aspergillosis, patients were initiated on IV Cresemba before transitioning to oral Cresemba therapy. 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 for patients classified as primary, 33 days for refractory, and 85 days for intolerant.

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.

Other Uses with Supportive Evidence

The National Comprehensive Cancer Network (NCCN) Guidelines for Prevention and Treatment of Cancer-Related Infections (version 1.2024 – April 30, 2024) note that use of Cresemba may be considered for patients who have invasive or refractory aspergillosis or mucormycosis or who have intolerance to amphotericin B formulations.[3] NCCN also notes Cresemba as a treatment option for the prevention of fungal infections in patients with significant graft-versus-host disease (GVHD) [especially grade 3/4] who are receiving immunosuppressive therapy; treatment should continue until resolution of significant GVHD. Cresemba is also a treatment option for these groups of patients with neutropenia: patients with myelodysplastic syndrome, patients with acute myeloid leukemia, and patients who are allogeneic hematopoietic cell transplant recipients; treatment should continue until resolution of neutropenia.

The guidelines for prevention and treatment of opportunistic infections in adults and adolescents with human immunodeficiency virus (HIV) infections (last updated July 2024) note Cresemba as a treatment option for patients with HIV and esophageal candidiasis.[4]

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 one of 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. **Candidiasis (Systemic) in a Patient with Human Immunodeficiency Virus (HIV) Infection – Treatment.** Approve for 3 months.

4. **Fungal Infection (Systemic) in a Patient With Cancer and Neutropenia – Prophylaxis.** Approve for 6 months.
   Note: Examples of cancers predisposing neutropenic patients to risk of fungal infections include: myelodysplastic syndrome, acute myeloid leukemia, patients post-allogeneic hematopoietic cell transplant.

5. **Fungal Infection (Systemic) in a Patient with Graft-versus-Host Disease – Prophylaxis**. Approve for 6 months.

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

7. **Patient is Currently Receiving Cresemba.** 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; December 2023.
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. The NCCN Prevention and Treatment of Cancer-Related Infections Clinical Practice Guidelines in Oncology (version 1.2024 – April 30, 2024). ©2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 25, 2024.
4. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: 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. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf. Last updated July 9, 2024. Accessed on July 25, 2024.