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Isavuconazonium (Oral)

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Overview

This policy supports medical necessity review for oral isavuconazonium (Cresemba®).

This coverage policy only addresses the use of oral isavuconazonium. The use of intravenous isavuconazonium is not addressed in this coverage policy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Isavuconazonium (Cresemba) is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, or 7):

- 1. Treatment of Invasive Aspergillus Infection.
2. Treatment of Invasive Mucormycosis.

3. **Treatment of systemic Candidiasis in an individual with Human Immunodeficiency Virus (HIV) Infection.**
4. **Treatment of systemic fungal infection that is susceptible to Isavuconazonium (Cresemba).**
5. **Prophylaxis against systemic fungal infection in an individual with Cancer and Neutropenia.**
6. **Prophylaxis against systemic fungal infection in an individual with Graft-versus-Host Disease.**
7. **Continuation of therapy for individuals currently receiving Isavuconazonium (Cresemba) to complete a course of therapy.**

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Isavuconazonium (Cresemba) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:

- **Prophylaxis against systemic fungal infection in an individual with Cancer and Neutropenia:** up to 6 months
- **Prophylaxis against systemic fungal infection in an individual with Graft-versus-Host Disease:** up to 6 months
- **All other indications:** up to 3 months

Reauthorization approval duration:

- **Prophylaxis against systemic fungal infection in an individual with Cancer and Neutropenia:** up to 6 months
- **Prophylaxis against systemic fungal infection in an individual with Graft-versus-Host Disease:** up to 6 months
- **All other indications:** up to 3 months

Conditions Not Covered

Isavuconazonium (Cresemba) is considered experimental, investigational or unproven for **ANY** other use.

Background

OVERVIEW

Cresemba, an azole antifungal, is indicated in adults 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. 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.

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) Prevention and Treatment of Cancer-Related Infections (version 1.2022 – June 2, 2022) notes that use of Cresemba may be considered for patients as either primary or refractory therapy for invasive fungal infections; Cresemba may also be considered for use in patients with intolerance to amphotericin B formulations.³ NCCN also notes Cresemba as a treatment option for the prevention of fungal infections in patients who are allogeneic hematopoietic cell transplant recipients and have neutropenia.³ Treatment should be continued until neutropenia is resolved.

The guidelines for prevention and treatment of opportunistic infections in adults and adolescents with human immunodeficiency virus (HIV) infections (last updated April 2022) note Cresemba as a treatment option for patients with HIV and candidiasis (e.g., esophageal candidiasis).⁴

References

1. Cresemba® capsules [prescribing information]. Northbrook, IL: Astellas Pharma; November 2022.
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 1.2023 – June 28, 2023). ©2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 13, 2023.
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 June 14, 2023. Accessed on July 13, 2023.

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