

Policy: MBP 134.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Cresemba IV (isavuconazonium sulfate)

I. Policy:

Cresemba IV (isavuconazonium sulfate)

II. Purpose/Objective:

To provide a policy of coverage regarding Cresemba IV (isavuconazonium sulfate)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Cresemba IV (isavuconazonium sulfate) is an azole antifungal indicated for the treatment of invasive aspergillosis and for the treatment of invasive mucormycosis in patients 18 years of age and older.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Cresemba IV (isavuconazonium sulfate) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
 - Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis **OR** for the treatment of invasive mucormycosis

OR

- Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

AUTHORIZATION DURATION: Authorization duration should be for a length of 3 months. Reauthorization will be based on the following criteria:

- Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba **AND**
- Medical record documentation that the appropriate dose is being prescribed (1 vial/day)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Cresemba [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; December 2023.
2. Samanta P, Clancy CJ, Marini RV, et al. Isavuconazole Is as Effective as and Better Tolerated Than Voriconazole for Antifungal Prophylaxis in Lung Transplant Recipients [Internet]. Oxford Academic. Infectious Disease Society of America; 2020 [cited 2021 Jul 1]. Available from: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa652/5848270>
3. Bose P, McCue D, Wurster S, et al. Isavuconazole as Primary Antifungal Prophylaxis in Patients With Acute Myeloid Leukemia or Myelodysplastic Syndrome: An Open-label, Prospective, Phase 2 Study [Internet]. Oxford University Press. Infectious Diseases Society of America; 2021 [cited 2021 Jul 1]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8130026/>
4. Cornely OA, Böhme A, Schmitt-Hoffmann A, et al. Safety and Pharmacokinetics of Isavuconazole as Antifungal Prophylaxis in Acute Myeloid Leukemia Patients with Neutropenia: Results of a Phase 2, Dose Escalation Study [Internet]. Antimicrobial Agents and Chemotherapy. ASM Journals; 2015 [cited 2021 Jul 1]. Available from: <https://journals.asm.org/doi/10.1128/aac.04569-14?permanently=true>
5. Stern A, Su Y, Lee YJ, et al. A Single-Center, Open-Label Trial of Isavuconazole Prophylaxis against Invasive Fungal Infection in Patients Undergoing Allogeneic Hematopoietic Cell Transplantation [Internet]. Biology of blood and marrow transplantation. Journal of the American Society for Blood and Marrow Transplantation; 2020 [cited 2021 Jul 1]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8210627/>
6. Fontana L, Perlin DS, Zhao Y, et al. Isavuconazole Prophylaxis in Patients With Hematologic Malignancies and Hematopoietic Cell Transplant Recipients [Internet]. Clinical infectious diseases. Oxford University Press; 2020 [cited 2021 Jul 6]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7931837/>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/15/15

Revised: 7/20/21 (added prophylaxis indication), 8/19/22 (formatting, Medicaid PARP statement), 8/18/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added)

Reviewed: 9/14/16, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/28/21

MA UM Committee approval: 12/31/23, 5/22/24