

Clinical Policy: Isavuconazonium (Cresemba)
Reference Number: HIM.PA.108
Effective Date: 08/17
Last Review Date: XX/XX
Line of Business: Health Insurance Marketplace

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Isavuconazonium (Cresemba[®]) is an azole antifungal.

FDA approved indication

Cresemba is indicated:

- For the treatment of invasive aspergillosis
- For the treatment of invasive mucormycosis

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Aspergillosis (must meet all):

1. Diagnosis of aspergillosis;
2. Prescribed by or in consultation with an infectious disease specialist;
3. Confirmation of diagnosis through tissue histopathology and fungal culture exam;
4. Failure of a 12 week trial of voriconazole at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 372 mg every 8 hours for 48 hours (12 capsules/6 doses), then 372 mg/day (2 capsules/day).

Approval duration: 3 months

B. Mucormycosis (must meet all):

1. Diagnosis of mucormycosis;
2. Prescribed by or in consultation with an infectious disease specialist;
3. Confirmation of diagnosis through tissue histopathology;
4. Documentation of a 12 week trial of amphotericin B at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 372 mg every 8 hours for 48 hours (12 capsules/6 doses), then 372 mg/day (2 capsules/day).

Approval duration: 3 months

C. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Aspergillosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 372 mg/day (2 capsules/day).

Approval duration: 6 months

B. Mucormycosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 372 mg/day (2 capsules/day).

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents;**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

V. References

1. Cresemba Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; June 2015. Available at <https://www.cresemba.com/>. Accessed April 24, 2017.
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 Aug 15;63(4):e1-e60. doi: 10.1093/cid/ciw326.
3. Cox GM. Mucormycosis (zygomycosis). Kauffman CA (Ed), UpToDate. Waltham MA. Accessed April 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

CLINICAL POLICY

Isavuconazonium



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