Pharmacy Medical Necessity Guidelines: Cresemba (isavuconazonium) capsule

Effective: September 1, 2023

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

COVERAGE GUIDELINES

The plan may authorize coverage of Cresemba capsules when the following criteria are met:
The Member meets **ONE** of the following:

1. The Member was started on Cresemba (isavuconazonium) in the inpatient setting

OR

2. The Member has a diagnosis of invasive aspergillosis

AND

The Member had an inadequate response, intolerance, or contraindication to one of the following: Posaconazole OR voriconazole

OR

3. The Member has a diagnosis of invasive mucormycosis

AND

The Member had an inadequate response, intolerance, or contraindication to Posaconazole

LIMITATIONS

None

CODES

None

REFERENCES

1. Cox GM. Mucormycosis (zygomycoss). www.uptodate.com. Accessed 31 May 2023.
2. Cresemba (isavuconazonium) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2022.
3. Patterson TF. Treatment and prevention of invasive aspergillosis. www.uptodate.com. Accessed 31 May 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective September 1, 2023, updated criteria for invasive mucormycosis to include a trial with Posaconazole.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services