

AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Cresemba[®] (isavuconazonium sulfate) for injection (Medical) (J1833)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage in Adult Patients:

<u>Dosage Form</u>	<u>Loading Dose</u>	<u>Maintenance Dose*</u>	<u>Quantity Limit</u>
Injection, 372 mg/vial	One reconstituted vial (372 mg) intravenously every 8 hours for 6 doses (48 hours)	One reconstituted vial (372 mg) intravenously once daily	<ul style="list-style-type: none">• Loading Dose = 6 vials• Maintenance Dose = 30 vials/month

*Start maintenance doses 12 to 24 hours after the last loading dose

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Recommended Dosage in Pediatric Patients:

<u>Dosage Form</u>	<u>Age</u>	<u>Body Weight (kg)</u>	<u>Loading Dose</u>	<u>Maintenance Dose*</u>	<u>Maximum Quantity Limit</u>
Injection, 372 mg/vial	1 to < 3 years of age	< 18 kg	15 mg/kg intravenously every 8 hours for 6 doses (48 hours)	15 mg/kg intravenously once daily	<ul style="list-style-type: none"> • Loading Dose = 6 vials • Maintenance Dose = 30 vials/month
	3 to < 18 years of age	< 37 kg	10 mg/kg intravenously every 8 hours for 6 doses (48 hours)	10 mg/kg intravenously once daily	
		≥ 37 kg	One reconstituted vial (372 mg) intravenously every 8 hours for 6 doses (48 hours)	One reconstituted vial (372 mg) intravenously once daily	

*Start maintenance doses 12 to 24 hours after the last loading dose

- Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member’s ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 weeks

- Member is 1 year of age or older
- Member must meet **ONE** of the following:
 - Member has a diagnosis of invasive aspergillosis, and the member has a documented trial and failure, or contraindication, to voriconazole therapy as first line therapy
 - Member has a diagnosis of invasive mucormycosis
 - Member is completing a course of therapy that has been initiated in the hospital

Please provider date therapy was initiated (loading dose included) and how many days completed:

DATE: _____ **DAYS OF THERAPY COMPLETED:** _____

- Provider confirms the member is **NOT** on concurrent use of strong CYP3A4 inducers such as rifampin, carbamazepine, or St. John’s Wort
- Provider confirms the member is **NOT** on concurrent use of strong CYP3A4 inhibitors such as ketoconazole or high dose ritonavir
- Provider confirms the member does **NOT** have medical history of familial short QT syndrome

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Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member continues to meet all initial authorization criteria
- Member will require secondary prophylaxis to prevent disease recurrence of invasive aspergillosis or mucormycosis
- Liver function tests are being monitored, and the member is **NOT** experiencing clinical signs and symptoms of liver disease or hepatic failure

Medication being provided by: Please check applicable box below.

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

****Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****