

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: Rebyota[®] (fecal microbiota, live – jsml) (J1440) (Medical)

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 Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

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

☐ 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.

Quantity Limits & Billable Units: 150 mL (1 enema) per lifetime = 150 billable units per package

Diagnoses (ICD-10 codes):

- **A04.71:** Enterocolitis due to Clostridium difficile, recurrent
- **G0455:** Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

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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.

- ☐ Medication has been prescribed for the prevention of recurrent Clostridioides/Clostridium difficile infection (CDI)
- ☐ Member is 18 years of age or older
- ☐ Medication must be prescribed by or in consultation with **ONE** of the following specialists:
 - ☐ Infectious Disease
 - ☐ Gastroenterology
- ☐ Member has a diagnosis of CDI confirmed by **BOTH** of the following:
 - ☐ Diarrhea (3 or more loose bowel movements within 24 hours or less)
 - ☐ Positive stool test for toxigenic C. difficile from a stool sample collected within 30 days before request
- ☐ This episode of CDI is at least 1 recurrent episode of CDI (≥ 2 total CDI episodes) in the past 6 months with previous treatment (e.g., vancomycin, fidaxomicin, including a pulsed vancomycin regimen)
- ☐ Requested medication will be used after antibiotic treatment for recurrent CDI (e.g., within 24 to 72 hours following the last dose of antibiotic treatment)
- ☐ Member is considered “high risk” for initial CDI defined by meeting at least **ONE** of the following (**check all that apply**):
 - ☐ Age ≥ 65 years
 - ☐ History of 1 or more CDI episodes within the previous six months
 - ☐ Compromised immunity
 - ☐ Documentation of hypervirulent strain (strains 027, 078, 244)
 - ☐ Clinically severe CDI (defined by a Zar score of ≥ 2 points): Age > 60 years (1 point); Body temperature $> 38.3^{\circ}\text{C}$ (1 point); Albumin level 2.5 mg/dL (1 point); Peripheral white blood cell count $> 15,000 \text{ cells/mm}^3$ within 48 hours (1 point); Endoscopic evidence of pseudomembranous colitis (2 points); Treatment in Intensive Care Unit (2 points)

Medication being provided by (check applicable box(es) below):

- ☐ Physician's office OR ☐ Specialty Pharmacy

*****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.****