AvMed

PHARMACY 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 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Vowst™ (fecal microbiota spores, live-brpk)

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

Quantity Limit: 12 capsules (1 bottle) per 365 days

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.

- ❑ 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 Clostridium difficile infection (CDI) confirmed by **BOTH** of the following:
  - ❑ Diarrhea (defined as 3 or more loose bowel movements within 24 hours or less)
  - ❑ Positive stool test for toxigenic C. difficile from a stool sample collected no more than 7 days prior

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- ❑ Member has a confirmed diagnosis of recurrent CDI with a total of ≥ 3 episodes of CDI within the past 12 months **(submit documentation or verify previous antibiotic paid claims within the past 60 days)**
- ❑ Antibiotic treatment for recurrent CDI must be completed (10 days of treatment) 2 to 4 days prior to initiation of Vowst™ therapy (i.e., previous treatment with vancomycin, fidaxomicin, including a pulsed vancomycin regimen or Zinplava®)
- ❑ Member have tried and failed **BOTH** of the following:
  - ❑ Rebyota™ (fecal microbiota, live jslm) ***requires medical prior authorization***
  - ❑ Zinplava® (bezlotoxumab) ***requires medical prior authorization***
- ❑ 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°C (1 point); Albumin level 2.5 mg/dL (1 point); Peripheral white blood cell count > 15,000 cells/mm^3 within 48 hours (1 point); Endoscopic evidence of pseudomembranous colitis (2 points); Treatment in Intensive Care Unit (2 points)
- ❑ Provider will instruct member to take 10 oz of magnesium citrate (or 250 mL polyethylene glycol electrolyte solution for patients with impaired kidney function) the evening prior to initiation of Vowst™ therapy
- ❑ Member must **NOT** have an absolute neutrophil count (ANC) < 500 cells/mm^3, toxic megacolon, or small bowel ileus

Reauthorization: Coverage may **NOT** be renewed. Vowst is approved for one time use. Repeat administration has **NOT** been approved.

Medication being provided by Specialty Pharmacy – Proprium Rx

*****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.****