VENTURA COUNTY
HEALTH CARE PLAN

VOWST (Fecal Microbiota Spores, Live-brpk)

Effective Date: 11/7/2023

Date Developed: 11/1/23 by Howard Taekman, MD

Date Approved by P&T Committee: 11/7/2023, 2/13/24, 2/18/25

Description

Vowst is a suspension of live purified Firmacutes spores in capsules manufactured from human fecal matter sourced from qualified donors.

Firmicutes are Gram positive bacteria that include species belonging to the Clostridia class, as well as members of the Enterococcaceae and Lactobacillaceae families and Lactococcus species. They modulate bile acid concentrations and restore short chain fatty acids resulting in colonization resistance to C. difficile and restoration of intestinal eubiosis.

Authorization Criteria:

Vowst is indicated to prevention the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI.

NOTE: Vowst is not indicated for treatment of CDI.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Prevention of *Clostridioides difficile* Infection (must meet all):

1. Diagnosis of CDI confirmed by documentation of positive Clostridioides difficile test;
2. Age ≥ 18 years;
3. Member has recurrent CDI as evidenced by at least 2 episodes of CDI recurrence after a primary episode (i.e., total 3 episodes);
4. Member has received at least 10 consecutive days of antibiotic therapy for the current CDI (e.g., vancomycin, fidaxomicin);
5. The current CDI is controlled (< 3 unformed/loose stools/day for 2 consecutive days [i.e., diarrhea, or Bristol Stool Scale type 6-7]);
6. Vowst is prescribed with one of the following (a or b), administered prior to the first Vowst dose: a. Magnesium citrate; b. If member has impaired kidney function, polyethylene glycol electrolyte solution (e.g., generic GoLYTELY®);

7. Member has not previously received Vowst, Rebyota™, or prior fecal microbiota transplant;
8. Dose does not exceed 4 capsules per day for 3 consecutive days.

Approval duration: 3 months (1 treatment course only)

II. Continued Therapy

A. Prevention of *Clostridioides difficile* Infection

1. Re-authorization is not permitted as the efficacy of repeat courses of Vowst has not been sufficiently established.

Approval duration: Not applicable

V. Dosage and Administration

Indication

Prevention of CDI

Dosing Regimen

- 4 capsules PO QD for 3 consecutive days

Prior to taking the first Vowst dose:

- Complete antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with Vowst
- Drink 296 mL (10 oz) of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst. In clinical studies, participants with impaired kidney function received polyethylene glycol electrolyte solution (205 ml GoLYTELY)

VII. References

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7. Kelly CR, Fischer M, Allegretti JR, et al. ACG clinical guidelines: Prevention, diagnosis, and treatment of Clostridioides difficile infections. Am J Gastroenterol. 2021; 116: 1124 - 1147.

8. Caroff DA, Edelstein PH, Hamilton K, et al. The Bristol stool scale and its relationship to Clostridium difficile infection. J Clin Microbiol. 2014; 52(9): 3437-3439.

9. Martinez-Gili L, McDonald JAK, Liu Z, et al. Understanding the mechanisms of efficacy of fecal microbiota transplant in treating recurrent Clostridioides difficile infection and beyond: the contribution of gut microbial-derived metabolites. Gut Microbes. 2020;12(1):1810531.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
11/7/23	Created	Howard Taekman, MD; Robert Sterling, MD	NEW
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual Update
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated description and replaced “FDA Approved Indication” with Authorization criteria. References updated