Pharmacy Policy Bulletin: J-1290 Vowst (fecal microbiota spores, live-brpk) – Commercial and Healthcare Reform	
Number: J-1290	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1290-003	**Original Date:** 06/07/2023
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Vowst (fecal microbiota spores, live-brpk)
FDA-Approved Indication(s):	• Prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI (rCDI).

Background:	• Vowst is a fecal microbiota product. The mechanism of action has not been established. Vowst is composed of live purified *Firmicutes* bacterial spores, and it is theorized that these spore-forming bacteria compete metabolically with *C. difficile* for essential nutrients, modulate bile-acid profiles to reestablish resistance to colonization, or have both of these effects. • *C. difficile* is a bacterium that can cause colitis and results in diarrhea, fever, and nausea. CDI is contagious and can be life-threatening. In the United States, there are about 500,000 cases each year with 1 in 6 patients experiencing recurrent CDI within two to eight weeks following the initial CDI. About 1 in 11 patients over age 65 years with a healthcare-associated CDI die within one month. • Patients are at the highest risk for CDI during or after a course of broad-spectrum antibiotics. The most common antibiotics that can cause CDI include cephalosporins, clindamycin, fluoroquinolones, and penicillins, however, all antibiotics may pose a risk for causing CDI. Additional risk factors include age 65 years or older, recent hospital or nursing home stay, weakened immune system, and previous CDI. • rCDI is defined as an episode of symptom onset and positive assay result following a CDI episode with positive assay result in the previous 2 to 8 weeks. • The 2021 Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Guideline Update on Management of CDI in Adults recommends use of antibiotics for at least two CDI recurrences before using fecal microbiota transplantation (FMT). In patients with a rCDI episode, oral fidaxomicin or oral vancomycin are recommended for treatment.

	• The 2021 American College of Gastroenterology (ACG) Clinical Guidelines for the Prevention, Diagnosis, and Treatment of CDI recommends the use of FMT as prophylaxis for patients experiencing their second or subsequent recurrence of CDI. The guideline suggests repeating FMT for patients experiencing a CDI recurrence within eight weeks of the initial FMT.
	• Prescribing Considerations:
	  ○ Vowst is not indicated for the treatment of CDI.
	  ○ Vowst has warnings or precautions for risk of transmissible infectious agents and potential presence of food allergens.
	  ○ Vowst is stored at room temperature.
	  ○ Vowst is self-administered 48 to 96 hours after the conclusion of antibiotic treatment for CDI with antibiotics to be avoided during use.
	  ○ Vowst requires pre-medication with magnesium citrate on the day before and at least 8 hours prior to taking the first dose, or polyethylene glycol electrolyte solution if the patient has impaired renal function.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Vowst may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.

B. The member has had a recent diagnosis of *Clostridioides difficile* infection (CDI) (ICD-10: A04.71, A04.72) confirmed by a positive stool test.

C. The CDI is classified as recurrent (specifically ≥ 2 total CDI episodes).

D. The prescriber attests that the member will be using Vowst for prophylaxis and not treatment of recurrent CDI.

E. The member has completed or will complete antibiotic treatment (for example, oral vancomycin, oral fidaxomicin) for the most recent recurrent CDI

II. Reauthorization

When a benefit, reauthorization of Vowst may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member will be using Vowst for prophylaxis and not treatment of recurrent CDI.

B. The member has experienced recurrent CDI episodes after administration of the initial fecal microbiota product.

C. The member has completed or will complete antibiotic treatment (for example, oral vancomycin, oral fidaxomicin) for the most recent recurrent CDI

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 1 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics, Inc. February 2025.
2. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. *Am J Gastroenterol*. 2021;116(6):1124-1147.
3. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. *Clin Infect Dis*. 2021;73(5):e1029-e1044.
4. McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clin Infect Dis*. 2018;66(7):e1-e48.
5. CDC. About C. diff. Available at: https://www.cdc.gov/c-diff/about/index.html. Accessed April 29, 2025.
6. CDC. Nearly half a million Americans suffered from Clostridium difficile infections in a single year. Available at: https://www.cdc.gov/media/releases/2015/p0225-clostridium-difficile.html. Accessed April 29, 2025.
7. Mayo Clinic. C. difficile infection. Available at: https://www.mayoclinic.org/diseases-conditions/c-difficile/diagnosis-treatment/drc-20351697. Accessed April 29, 2025.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

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