Effective Date: 12/1/2023
Reviewed: 9/23, 5/24
Pharmacy Scope: Medicaid

VOWST (fecal microbiota spores, live-brpk)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Vowst is indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

Limitations of Use
Vowst is not indicated for the treatment of CDI.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Medical records, chart notes, and/or lab test results documenting the following:
   1. Recurrent CDI infection
   2. Stool test within 30 days confirming the presence of *C.difficile* toxin or toxigenic *C. difficile*

III. EXCLUSIONS

Coverage will not be provided for members requesting Vowst for the treatment of CDI.

IV. CRITERIA FOR INITIAL APPROVAL

Prevention of recurrence of Clostridioides difficile infection (CDI)[1]
Authorization of 30 days for a one-time treatment may be granted for prevention of CDI when all of the following criteria are met:
A. Member is 18 years of age and older
B. Medication is prescribed by or in consultation with an infectious disease specialist or gastroenterologist
C. Member has had three or more episodes of CDI within the past 12 months (including the most recent episode).
D. Member has a recent episode of recurrent CDI with all of the following:
   1. Stool test confirming the presence of *C.difficile* toxin or toxigenic *C. difficile*
   2. Treatment initiation with Vowst will occur 2-4 days after the last dose of at least 10 consecutive days of antibiotics for CDI treatment

3. Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days)

E. Member has experienced an inadequate response, intolerance, or contraindication to Zinplava (bezlotoxumab) or fecal microbiota transplantation (FMT) from a reputable source

V. RENEWAL CRITERIA

Coverage cannot be renewed.

VI. QUANTITY LIMIT

Vowst has a quantity limit of 12 capsules per 30 days.

Indication	Dose

Prevention of CDI	• 4 capsules orally once daily for 3 consecutive days
	• Take each dose (4 capsules) on an empty stomach prior to the first meal of the day.
	• Prior to taking the first dose:
	  ○ Complete antibacterial treatment for rCDI 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 (250 mL GoLYTELY, not approved for this use).

VII. REFERENCES

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics Inc; April 2023.
2. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 updated by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. March 2018;66(7):987-994.
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. CID 2021; 73 (1 September): e1029-1044.
4. 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.