

## 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. EXCLUSIONS

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

#### III. CRITERIA FOR INITIAL APPROVAL

##### **Prevention of recurrence of *Clostridioides difficile* infection (CDI)<sup>1</sup>**

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. Documentation that the member has recurrent CDI infection with either of the following:
  1. Member has at least one reoccurrence after a primary episode and has completed at least 1 round of standard of care oral antibiotic therapy (e.g., metronidazole, fidaxomicin)
  2. Member has had at least 2 episodes of severe CDI resulting in hospitalization within the past 12 months
- D. Member has a recent episode of recurrent CDI with documentation of 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)

#### IV. RENEWAL CRITERIA

Coverage cannot be renewed.

#### V. QUANTITY LIMIT

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

Indication	Dose
Prevention of CDI	<ul style="list-style-type: none"> <li>• 4 capsules orally once daily for 3 consecutive days</li> <li>• Take each dose (4 capsules) on an empty stomach prior to the first meal of the day.</li> <li>• Prior to taking the first dose: <ul style="list-style-type: none"> <li>○ Complete antibacterial treatment for rCDI 2 to 4 days before initiating treatment with Vowst.</li> <li>○ 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).</li> </ul> </li> </ul>

#### VI. REFERENCES

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics Inc; March 2025. Accessed June 2025.
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, Laverigne 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.