Reference number(s)
5922-A

SPECIALTY GUIDELINE MANAGEMENT

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 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)
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. Member has had three or more episodes of CDI within the past 12 months (including the most recent episode).
C. Member has a recent episode of recurrent CDI with all of the following:
   1. At least 3 unformed stools per day for 2 consecutive days
   2. Stool test confirming the presence of *C.difficile* toxin or toxigenic *C. difficile*
   3. An adequate clinical response (e.g., resolution of symptoms) following standard of care antibiotic therapy (e.g., vancomycin, fidaxomicin).

V. REFERENCES

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics Inc; April 2023.