

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2310-2
Program	Prior Authorization/Medical Necessity
Medication	Vowst™ (fecal microbiota spores, live-brpk)
P&T Approval Date	7/2023, 12/2023
Effective Date	3/1/2024

1. Background:

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).

2. Coverage Criteria^a:

A. Authorization

1. Vowst will be approved based on **all** of the following criteria:

a. Diagnosis of recurrent Clostridioides difficile infection (rCDI) as defined by both of the following:

- (1) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- (2) A positive stool test for Clostridioides difficile toxin

-AND-

b. Patient is 18 years of age or older

-AND-

c. Patient has had one or more recurrence(s) of CDI following an initial episode of CDI

-AND-

d. Patient has had a failure, contraindication, or intolerance to Rebyota for the prevention of rCDI

-AND-

e. Patient has completed at least 10 days of one of the following antibiotic therapies for rCDI 2 to 4 days prior to initiating Vowst[^]:

- (1) Oral vancomycin
- (2) Dificid (fidaxomicin)

-AND-

f. Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days]

-AND-

g. Patient will drink magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst

-AND-

h. Prescribed by or in consultation with one of the following:

- (1) Gastroenterologist
- (2) Infectious disease specialist

Authorization will be issued for 1 month

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[^]Tried/failed alternative(s) are supported by FDA labeling.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply.

4. References:

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

Program	Prior Authorization/Medical Necessity – Vowst (fecal microbiota spores, live-brpk)
Change Control	
Date	Change
7/2023	New program.
12/2023	Updated criteria to lower the number of required recurrent CDI. Updated antibiotic course requirement. Added requirement of failure, contraindication, or intolerance to Rebyota.