UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2310-3
Program	Prior Authorization/Medical Necessity
Medication	Vowst™ (fecal microbiota spores, live-brpk)
P&T Approval Date	7/2023, 12/2023, 12/2024
Effective Date	3/1/2025

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.; June 2024.

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.
12/2024	Annual review. Updated reference.