PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Vowst (fecal microbiota spores, live-brpk)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vowst is a capsule for oral administration indicated to prevent recurrence of *Clostridioides difficile* infection (CDI) in patients 18 years and older following antibacterial treatment for recurrent CDI. Vowst is the first FDA approved fecal microbiota product for oral administration. Antibiotics including vancomycin and fidaxomicin are effective at treating CDI, however symptoms recur in ~15% of patients. Preceding FDA approval of Vowst and Rebyota, Fecal Microbiota Transplantation (FMT) from donor stool administered via colonoscopy was used for prevention of recurrent CDI.

Vowst (fecal microbiota spores, live-brpk) will be considered for coverage when the following criteria are met:

Prevention of recurrence of *Clostridioides difficile* infection (CDI)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist; AND
3. Member has documentation of one or more recurrences of CDI (two or more episodes); AND
4. Member has a positive stool test for the presence of *Clostridioides difficile* within the past 30 days; AND
5. Member has had a trial and failure of Rebyota; AND
6. Member has completed or will have completed an appropriate antibiotic treatment regimen (i.e., vancomycin, fidaxomicin, or metronidazole) for recurrent CDI 2-4 days prior to initiating treatment supported by claims history and/or provider documentation; AND
7. Vowst is not prescribed for the treatment of CDI.
8. **Dosage allowed/Quantity limit**: 4 capsules orally once daily for 3 days. QL: 12 capsules.

If all the above requirements are met, one course of the medication will be approved.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Vowst (fecal microbiota spores, live-brpk) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/09/2023	New policy for Vowst created.
07/13/2023	Added trial of Rebyota.

References:

1. Vowst. Package Insert. Seres Therapeutics, Inc.; 2023. Accessed May 11, 2023.
2. McDonald LC, Gerding DN, Johnson S, Bakken JS, Carroll KC, Coffin SE, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018 Feb 15;66(7):1-48. https://doi.org/10.1093/cid/cix1085
3. Feuerstadt P, Louie TJ, Lashner B, et al. SER-109, an Oral Microbiome Therapy for Recurrent Clostridioides difficile Infection. N Engl J Med. 2022;386(3):220-229. doi:10.1056/NEJMoa2106516
4. Cohen SH, Louie TJ, Sims M, et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. 2022;328(20):2062-2064. doi:10.1001/jama.2022.16476
5. Sims MD, Khanna S, Feuerstadt P, et al. Safety and Tolerability of SER-109 as an Investigational Microbiome Therapeutic in Adults With Recurrent Clostridioides difficile Infection: A Phase 3, Open-Label, Single-Arm Trial. JAMA Netw Open. 2023;6(2):e2255758. Published 2023 Feb 1. doi:10.1001/jamanetworkopen.2022.55758

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