VENTURA COUNTY
HEALTH CARE PLAN

VOWST (Fecal Microbiota Spores, Live-brpk)

Effective Date: 11/7/2023

Date Developed: 11/1/23 by Howard Taekman, MD

Last Approval Date: 11/7/2023

Description

Fecal microbiota spores, live-brpk (Vowst™) is a bacterial spore suspension in capsules manufactured from human fecal matter sourced from qualified donors.

FDA Approved Indication(s)

Vowst is indicated to prevention the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI.

Limitation(s) of use: Vowst is not indicated for treatment of CDI.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Prevention of *Clostridioides difficile* Infection (must meet all):

1. Diagnosis of CDI confirmed by documentation of positive Clostridioides difficile test;
2. Age ≥ 18 years;
3. Member has recurrent CDI as evidenced by at least 2 episodes of CDI recurrence after a primary episode (i.e., total 3 episodes);
4. Member has received at least 10 consecutive days of antibiotic therapy for the current CDI (e.g., vancomycin, fidaxomicin);
5. The current CDI is controlled (< 3 unformed/loose stools/day for 2 consecutive days [i.e., diarrhea, or Bristol Stool Scale type 6-7]);
6. Vowst is prescribed with one of the following (a or b), administered prior to the first Vowst dose: a. Magnesium citrate; b. If member has impaired kidney function, polyethylene glycol electrolyte solution (e.g., generic GoLYTELY®);
7. Member has not previously received Vowst, Rebyota™, or prior fecal microbiota transplant;
8. Dose does not exceed 4 capsules per day for 3 consecutive days.

Approval duration: 3 months (1 treatment course only)

II. Continued Therapy

A. Prevention of *Clostridioides difficile* Infection

1. Re-authorization is not permitted as the efficacy of repeat courses of Vowst has not been sufficiently established (see Appendix A).

Approval duration: Not applicable

Appendix A: General Information

- Both the Infectious Diseases Society of America (IDSA) and the American College of Gastroenterology recommend fecal microbiota transplantation for patients experiencing their second or further recurrence of CDI.
- Approximately 35% of CDI patients experience recurrence after the initial treatment and resolution of diarrhea. Of those who have a primary recurrence, 40% will have another CDI episode, and after 2 recurrences, the chance of an additional episode increases to as high as 65%.
- Per the 2017 IDSA Clinical Practice Guidelines for CDI:
    - An incident case is one with a new primary symptom onset (i.e., in the previous 8 weeks, there was not an episode of positive symptoms with positive Clostridioides difficile result) and positive Clostridioides difficile assay result.
    - A recurrent infection is an episode of symptom onset with a positive assay result following an episode with positive assay result in the previous 2-8 weeks.
- Per the 2021 IDSA Focused Update for CDI in Adults:
    - Fidaxomicin is the preferred first-line treatment for patients with recurrent CDI episodes.
    - Vancomycin (in a tapered and pulsed regimen or as a standard course) is an alternative treatment for CDI recurrence.
    - o Bezlotoxumab (Zinplava®) is an adjunctive treatment that may be used in addition to standard of care antibiotics for patients with a recurrent CDI episode within the last 6 months.
    - Prior to fecal microbiota transplantation, appropriate antibiotic treatments for at least 2 recurrences (i.e., 3 CDI episodes) should be tried.
    - Examples of treatment regimens for recurrence:
        - Vancomycin 125 mg PO QID for 10 days (may be followed by rifaximin 400 mg PO TID for 20 days)
        - Tapered and pulsed regimens of vancomycin (e.g., vancomycin PO 125 mg QID for 10 to 14 days, then BID for 1 week, then QD for 1 week, then every 2 or 3 days for 2 to 8 weeks)
        - Fidaxomicin 200 mg PO BID for 10 days
        - Fidaxomicin 200 mg PO BID for 5 days followed by once every other day for 20 days
        - Fecal microbiota transplantation
        - Bezlotoxumab 10 mg/kg IV once during administration of standard of care antibiotics
- The Bristol Stool Scale is a tool to define stool types. Types 1-2 indicate constipated stool. Types 6-7 indicate diarrheal stool.
    - Type 1: separate hard lumps, like nuts
    - Type 2: sausage-shaped but lumpy
    - Type 3: like a sausage but with cracks on its surface
    - Type 4: like a sausage or snake, smooth and soft

    - Type 5: soft blobs with clear-cut edges (passed easily)
    - Type 6: fluffy pieces with ragged edges, a mushy stool
    - Type 7: watery, no solid pieces (entirely liquid)
- Repeat courses: In the event of treatment failure (i.e., CDI diarrhea) within the first 8 weeks of blinded treatment, participants in the ECOSPOR III phase 3 study were allowed to receive an open-label second treatment course of Vowst. However, only 4/89 (4.5%) patients who received an initial course of Vowst received this second course. All 4 of these patients ultimately achieved treatment success as week 8 and 12. At week 24, one of the 4 patients experienced a recurrence. Given that this was an open-label treatment and included a relatively small sample, this is considered insufficient data to support a second treatment course at this time.

V. Dosage and Administration

Indication

Prevention of CDI

Dosing Regimen

- 4 capsules PO QD for 3 consecutive days

Maximum Dose

See regimen

Prior to taking the first Vowst dose:

- Complete antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with Vowst
- 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 (205 ml GoLYTELY)

VII. References

1. Vowst Prescribing Information. Cambridge, MA: Seres Therapeutics, Inc.; April 2023. Available at: www.vowst.com. Accessed May 10, 2023.
2. Feuerstadt P, Louie TJ, Lashner B, et al. SER-109, an Oral Microbiome Therapy for Recurrent Clostridioides difficile Infection. N Engl J Med. 2022 Jan 20; 386(3):220-229.
3. 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 Feb 1; 6(2): e2255758.
4. Lessa FC, Mu Y, Bamber WM et al. Burden of Clostridium difficile infection in the United States. N Engl J Med. 2015 Feb 26;372(9):825-34. doi: 10.1056/NEJMoa1408913
5. 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.
6. Johnson S, Lavergne 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.
7. 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.
8. Caroff DA, Edelstein PH, Hamilton K, et al. The Bristol stool scale and its relationship to Clostridium difficile infection. J Clin Microbiol. 2014; 52(9): 3437-3439.

Revision History:
Date Reviewed/No Updates: 11/7/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 11/7/23

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
11/7/23	No	Howard Taekman, MD; Robert Sterling, MD	NEW