

**Generic Name:**

**Therapeutic Class or Brand Name:** Fecal Microbiota

**Applicable Drugs:** Rebyota (fecal microbiota, live - jslm), Vowst (fecal microbiota spores, live-brpk)

**Preferred:** N/A

**Non-preferred:** Vowst (fecal microbiota spores, live-brpk)

**VSI Excluded Drugs:** Rebyota (fecal microbiota, live - jslm)

**Date of Origin:** 2/24/2025

**Date Last Reviewed / Revised:** 2/24/2025

### PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IX are met)

- I. Documented diagnosis of recurrent *Clostridioides difficile* infection (CDI) with all of the following:
  - A. Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
  - B. A positive stool test for *Clostridioides difficile* toxin via enzyme immunoassay (EIA) within the previous 30 days. Use of polymerase chain reaction (PCR) is not accepted.
- II. History of at least 2 recurrent CDI episodes (ie, 3 total CDI episodes) OR documentation of severe or fulminant CDI in a patient who is a poor surgical candidate
- III. Documentation that the member's CDI is refractory to standard antibiotic therapy with clinically significant treatment failure, intolerance, or contraindication to both oral vancomycin and Difid (fidaxomicin).
- IV. Current episode of CDI must be controlled with less than 3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of oral antibiotic therapy
- V. Documentation of reasons why fecal microbiota transplantation (FMT) is not appropriate or unavailable.
- VI. Minimum age requirement: 18 years old
- VII. Treatment must be prescribed by or in consultation with an infectious disease specialist or gastroenterologist.
- VIII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- IX. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

## EXCLUSION CRITERIA

- History or presence of bowel diseases (e.g., toxic megacolon, irritable bowel syndrome, or inflammatory bowel diseases)
- History of major gastrointestinal surgery
- History of bariatric surgery
- History of prior fecal microbiota transplantation
- Documentation of frequent antibiotics or long-term antibiotic prophylaxis.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Rebyota: one 150 mL dose
- Vowst: 12 capsules

## APPROVAL LENGTH

- **Authorization:** 1 treatment course
- **Re-Authorization:** A second treatment course may be approved with letter of medical necessity or updated clinic notes from infectious disease consult

## APPENDIX

- N/A

## REFERENCES

1. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections [published correction appears in *Am J Gastroenterol*. 2022 Feb 1;117(2):358. doi: 10.14309/ajg.0000000000001529]. *Am J Gastroenterol*. 2021;116(6):1124-1147. doi:10.14309/ajg.0000000000001278
2. 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. *Clin Infect Dis*. 2021;73(5):e1029-e1044. doi:10.1093/cid/ciab549
3. Peery AF, Kelly CR, Kao D, et al. AGA clinical practice guideline on fecal microbiota-based therapies for select gastrointestinal diseases. *Gastroenterology*. 2024;166(3):409-434. doi:10.1053/j.gastro.2024.01.008
4. Rebyota. Prescribing information. Ferring Pharmaceuticals Inc; 2022. Accessed January 6, 2025. [https://www.ferringusa.com/wp-content/uploads/sites/12/2022/12/9009000002\\_REBYOTA-PI\\_11-2022.pdf](https://www.ferringusa.com/wp-content/uploads/sites/12/2022/12/9009000002_REBYOTA-PI_11-2022.pdf)
5. Vowst. Prescribing information. Seres Therapeutics, Inc; 2023. Accessed December 15, 2024. [https://www.vowst.com/sites/default/files/2024-08/VOWST\\_PI-062024.pdf](https://www.vowst.com/sites/default/files/2024-08/VOWST_PI-062024.pdf)

**MEDICATION POLICY:**  
(Microbiota-based Live Biotherapeutics)



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**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.