AdvancedHealth
Bridging the Future of Healthcare

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

Fecal Microbiota Drug Use Criteria

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Includes:

Rebyota© *(fecal microbiota, live-jslm)*
Vowst© *(fecal microbiota spores, live)*

GUIDELINE FOR USE:

Initial Request:

1. Does the patient have a confirmed diagnosis of recurrent Clostridioides difficile (C. diff) infection (CDI) with a history of at least two recurrent episodes (initial episode + a minimum of two recurrences)? Note: Recurrent CDI is defined as a resolution of CDI symptoms while on appropriate therapy, followed by a reappearance of symptoms within 8 weeks of discontinuing treatment.
    a. If yes, go to 2
    b. If no, deny as not meeting criteria

2. Is the current episode of CDI controlled, defined as less than three unformed or loose stools per day for two consecutive days?
    a. If yes, go to 3
    b. If no, deny as not meeting criteria

3. Has the patient previously been treated with each of the following agents in the setting of CDI recurrence: (a) Vancomycin or Fidaxomicin (Dificid) AND (b) Zinplava (Bezlotoxumab) or Fecal Microbiota Transplantation (FMT)
    a. If yes, go to 4
    b. If no, deny as not meeting criteria

4. Is the request for Vowst?
    a. If yes, go to 5
    b. If no, go to 6

5. Has the patient experienced treatment failure with agents listed in #3 above **AND** Rebyota?
    a. If yes, go to 6
    b. If no, deny as not meeting criteria. Documented treatment failure with frist-line treatment agents AND Rebyota is required.

6. Has a positive stool test for C. diff been documented within the last 30 days?
    a. If yes, go to 7
    b. If no, deny as not meeting criteria

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7. Is the medication prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist?
    a. If yes, go to 8
    b. If no, deny s not meeting criteria

8. Is the patient 18 years of age or older?
    a. If yes, go to 9
    b. If no, deny as not meeting criteria

9. Is the request for retreatment with Vowst?
    a. If yes, deny as criteria not met. Retreatment with Vowst is not covered
    b. If no, go to 10

10. Is the request within the coverage duration limit of one month with no reauthorization unless otherwise specified?
    a. If yes, approve for 1 month
    b. If no, deny as not meeting criteria

Rationale: To define a process for covering agents used in the treatment of recurrent CDI that is consistent with clinical practice guidelines and medical evidence while ensuring that less costly formulary options are trialed first.

FDA Approved Indications: To prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Oral fecal microbiota capsules are not indicated for treatment of CDI.

Mechanism of Action: The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI.

References:

1. Seres Therapeutics, Inc. (2023). *Vowst (fecal microbiota spores, live-brpk) Prescribing Information*. U.S. Food and Drug Administration.
2. Infectious Diseases Society of America (IDSA) & Society for Healthcare Epidemiology of America (SHEA). (2021). *Clinical Practice Guidelines for Clostridioides difficile Infection in Adults and Children*. *Clinical Infectious Diseases, 73*(5), e1029–e1044. DOI: 10.1093/cid/ciab549.
3. Kelly, C. P., Fischer, M., Allegretti, J. R., & Khanna, S. (2023). *Clostridioides difficile Infection: Prevention and Treatment Strategies*. *The New England Journal of Medicine, 388*(1), 42–53. DOI: 10.1056/NEJMra2207781.
4. 4. U.S. Centers for Disease Control and Prevention (CDC). (2023). *Clostridioides difficile Infection: Treatment Guidelines and Prevention Strategies*.
5. Internal Policy Document. (2024). *Vowst Drug Use Criteria.* Retrieved from PS Vowst Drug Use Criteria.pdf.