Rebyota™ (fecal microbiota, live-jslm)

When requesting Rebyota™ (fecal microbiota, live-jslm), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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

Coverage Guidelines

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

The individual must meet all of the following criteria for authorization:

- Is 18 years of age or older;
- Has a confirmed diagnosis of CDI defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days and a positive stool test for *C. difficile* toxin or toxigenic *C. difficile;*
- Meets one of the following:
    - Has had at least 3 episodes of CDI; OR
    - Within the past year, had at least 2 episodes of severe CDI resulting in hospitalization;
- The current CDI is under control (i.e., less than 3 loose stools per day for 2 consecutive days) after completing at least 10 consecutive days of antibiotic therapy;
- Has not previously received Rebyota.

Approval duration: One dose

Dosing Recommendation

The recommended Rebyota dosage is a single dose of 150 mL administered rectally.

Rebyota should be administered 24 to 72 hours after the last dose of antibiotics for CDI.

References

1. Rebyota [prescribing information]. Roseville, MN. Ferring Pharmaceuticals by Rebiotix, Inc. November 2022.
2. Feuerstadt P, Harvey A, Yoho DS, et al. Retrospective Analysis of the Safety and Efficacy of Fecal Microbiota, Live-jslm (REBYOTA™) Administered Under Enforcement Discretion to Patients With *Clostridioides difficile* Infection. *Open Forum Infectious Diseases* (2023). Available at: https://doi.org/10.1093/ofid/ofad171. Accessed on June 2024.

3. Khanna S, Assi M, Lee C, et al. Efficacy and Safety of RBX2660 in PUNCH CD3, a Phase III, Randomized, Double-Blind, Placebo-Controlled Trial with a Bayesian Primary Analysis for the prevention of Recurrent *Clostridioides difficile* Infection*. Drugs.* 2022;82:1527-1538.
4. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guidelines 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. [published online] June 2021. Accessed on June 28, 2024.

