Corporate Medical Policy: Fecal Microbiota, Live - jslm (Rebyota®) **"Notification"** **POLICY EFFECTIVE OCTOBER 1, 2026**

Restricted Product(s):

- fecal microbiota, live - jslm (Rebyota®) rectal suspension for administration by a healthcare professional

FDA Approved Use:

- For the prevention of recurrence of *Clostridioides difficile* infection (CDI) in patients 18 years of age and older, following antibiotic treatment for recurrent CDI
- Limitation of use: Not indicated for treatment of CDI

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient has a diagnosis of recurrent ***Clostridioides difficile* infection (CDI)**, as confirmed by BOTH of the following:
    a. Passage of three or more loose stools within a 24-hour period for 2 consecutive days; **AND**
    b. Positive stool test for *Clostridioides difficile* toxin or toxigenic *Clostridioides difficile* from a stool sample collected within the past 30 days **[medical record documentation required]**; **AND**
3. ONE of the following **[medical record documentation required]**:
    a. The patient has had at least one CDI recurrence after a primary episode (i.e., ≥2 total CDI episodes), e.g., occurring within 8 to 12 weeks of completing treatment for a prior CDI episode, and has completed at least one round of standard-of-care oral antibiotic therapy for CDI (e.g., fidaxomicin, oral vancomycin); **OR**
    b. The patient has had at least two episodes of severe CDI resulting in hospitalization within the last 12 months; **AND**
4. The patient has completed at least 10 consecutive days of antibiotic therapy for the current CDI; **AND**
5. The patient's CDI is under control after completing antibiotic therapy, as defined by less than 3 unformed/loose stools per day (i.e., Bristol Stool Scale type 6-7) for 2 consecutive days; **AND**
6. A minimum of 24 hours to a maximum of 72 hours have passed since the patient received the last dose of antibiotics for CDI; **AND**
7. The patient will be receiving the requested agent to prevent recurrence of CDI; **AND**
8. The patient has NOT had a previous fecal microbiota transplant; **AND**
9. The patient will NOT receive the requested agent in combination with fecal microbiota spores, live-brpk (Vowst); **AND**
10. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, infectious disease specialist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**

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11. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

Duration of Approval: 30 days (one-time approval for single dose)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
fecal microbiota, live – jslm (Rebyota®) rectal suspension	Prevention of recurrence of *Clostridioides difficile* infection (CDI) in patients ≥ 18 years old, following antibiotic treatment for recurrent CDI	Administer a single dose of 150 mL rectally 24 to 72 hours after the last dose of antibiotics for CDI	J1440	150

***Maximum units allowed for duration of approval**

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Dubberke ER, Orenstein R, Khanna S, et al. Final results from a phase 2b randomized, placebo-controlled clinical trial of RBX2660: a microbiota-based drug for the prevention of recurrent Clostridioides difficile infection. *Infect Dis Ther*. 2023 Feb;12(2):703-709.
2. Fischer M, Vaughn BP, Peery AF, et al. AGA clinical practice update on management of Clostridioides difficile infection in adults: expert review. *Clin Gastroenterol Hepatol*. 2026 Jun 30:S1542-3565(26)00358-7. Epub ahead of print.
3. 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. *Clinical Infectious Diseases*. 2021;73(5):e1029–e1044.
4. 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 Oct;82(15):1527-1538. Erratum in: *Drugs*. 2022 Oct;82(15):1539.
5. Peery AF, Kelly CR, Kao D, et al. AGA clinical practice guideline on fecal microbiota–based therapies for select gastrointestinal diseases. *Gastroenterology*. 2024 Mar;166(3):409-434.

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Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

October 2026: Criteria change: Reformatted prior CDI episode/recurrence requirements to include a timeframe between episodes to distinguish recurrence from reinfection, added examples of standard-of-care antibiotics, and added medical record documentation requirements. Added requirement that the patient will not use Rebyota in combination with Vowst. Added specialist requirement and maximum units criterion to align with unit requirements in the dosing reference table. **Policy notification given 8/3/2026 for effective date 10/1/2026**.
January 2024: Criteria change: Added requirement that positive stool test for *Clostridioides difficile* toxin or toxigenic *Clostridioides difficile* must be within the past 30 days. **Policy notification given 11/1/2023 for effective date 1/1/2024**.
July 2023: Coding change: Added HCPCS code J1440 to dosing reference table effective 7/1/2023; deleted C9399, J3490, and J3590 termed 6/30/2023.
February 2023: Original medical policy criteria issued.

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