Corporate Medical Policy: Fecal Microbiota, Live - jslm (Rebyota™) **"Notification"** **POLICY EFFECTIVE JANUARY 1, 2024**

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:
    a. The patient has had at least one CDI recurrence after a primary episode and has completed at least one round of standard-of-care oral antibiotic therapy for CDI; **OR**
    b. The patient has had at least two episodes of severe CDI resulting in hospitalization within the last year; **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.

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**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

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

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.

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.