

**C. difficile Prevention Agents**  
**Rebyota (fecal microbiota, live-jslm)**  
**Effective 06/01/2025**

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Rebyota is also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.		

### Overview

Rebyota (fecal microbiota, live-jslm) is a rectally administered fecal microbiota transplantation (FMT) for the prevention of recurrence of Clostridioides difficile infection (CDI) in patients 18 years of age or older following antibiotic treatment for recurrent CDI.

### Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis for prevention of recurrent CDI with  $\geq$  one episode of CDI following initial infection ( $\geq$  two total episodes of CD including initial infection)
2. Prescriber is an infectious disease specialist or gastroenterologist or consult notes from a specialist are provided
3. Member is  $\geq$  18 years of age
4. Medical necessity for requested agent instead of fecal microbiota transplant via other methods (e.g., IND protocol, stool banks)†
5. Requested quantity is  $\leq$  single, one time dose

† Contraindication to or patient unwillingness to undergo colonoscopy are acceptable medical necessities to bypass FMT via other methods

### Limitations

1. Initial approvals will be granted for 1 month.
2. Reauthorizations of Rebyota (fecal microbiota, live-jslm) will not be granted as it has not been studied for greater than a one-time administration.

### References

1. Rebyota (fecal microbiota, live -jslm) [package insert]. Roseville, MN: Ferring Pharmaceuticals Inc.; Dec 2024.

**Review History**

05/10/2023 - Created for P&T. New drug, Rebyota (fecal microbiota, live-jslm), will now have a prior authorization. Effective 6/5/23.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB. Effective 6/30/23.

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Diagnosis was updated to require two total episodes of CD including initial infection. Effective 6/1/25

