

**Rebyota® (fecal microbiota, live-jslm)**  
**Effective 06/30/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### 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  $\geq$  two episodes of CDI following initial infection ( $\geq$  three 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. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response, adverse reaction, or contraindication to Zinplava® (bezlotoxumab)
5. Medical necessity for requested agent instead of fecal microbiota transplant via other methods (e.g., IND protocol, stool banks)‡
6. Requested quantity is  $\leq$  single dose

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

### Limitations

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

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.; January 2023.

**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.

