

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

Plan	<ul> <li>☑ MassHealth UPPL</li> <li>□ Commercial/Exchange</li> </ul>		<ul> <li>☑ Prior Authorization</li> <li>□ Quantity Limit</li> <li>□ Step Therapy</li> </ul>
Benefit	<ul><li>☑ Pharmacy Benefit</li><li>☑ Medical Benefit</li></ul>	Program Type	
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

#### Overview

Rebyota<sup>®</sup> (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 ≥ two episodes of CDI following initial infection (≥ 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<sup>®</sup> (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

<sup>‡</sup> 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<sup>®</sup> (fecal microbiota, live–jslm) will not be granted as it has not been studied for greater than a one-time administration.

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

### References

1. Rebyota<sup>®</sup> (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.