

## fecal microbiota live-jslm (Rebyota)

### Commercial Medical Benefit Drug Policy

#### Drug Details

**USP Category:** MISCELLANEOUS THERAPEUTIC AGENTS

**Mechanism of Action:** Fecal microbiota suspension

**HCPCS:**

J1440:Fecal microbiota, live - jslm, 1 ml

**How Supplied:**

150 mL single dose suspension

#### Condition(s) listed in policy *(see coverage criteria for details)*

- Prevention of Recurrence of Clostridioides Difficile Infection (CDI)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

#### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

#### Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

**Prevention of Recurrence of Clostridioides Difficile Infection (CDI)**

**Meets medical necessity if all the following are met:**

1. Patient is  $\geq$  18 years of age
2. Patient has had 3 or more episodes of C.difficile infection
3. Patient is completing antibiotic therapy for C.difficile infection before starting Rebyota

**Covered Doses:**

150 mL administered rectally for one dose

**Coverage Period:**

Allow for one-time dose

**ICD-10:**

A04.71, A04.72

#### References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

3. Rebyota (fecal microbiota, live-jslm) Prescribing Information. Ferring Pharmaceuticals, Roseville, MN: 11/2022.

#### **Review History**

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- no clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*