Fecal microbiota, live-jslm (Rebyota™)

<u>Place of Service</u> Office Administration Outpatient Facility Administration

HCPCS: J1440 per 1 ml

Condition(s) listed in policy (see criteria for details)

• Prevention of recurrence of Clostridioides difficile infection (CDI)

AHFS therapeutic class: Gastrointestinal Agents

Mechanism of action: Fecal microbiota suspension

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for RebyotaTM (fecal microbiota, live-jslm) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Prevention of recurrence of Clostridioides difficile infection (CDI)

- Patient is ≥ 18 years of age, AND
- 2. Patient has had 3 or more episodes of C.difficile infection, AND
- 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

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice

All requests for RebyotaTM (fecal microbiota, live-jslm) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

• 150 mL single-dose suspension

(6) References

PHP Medi-Cal fecal microbiota, live-jslm (Rebyota™)

Effective: 01/31/2024 Page 1 of 2

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- RebyotaTM (fecal microbiota, live-jslm) [Prescribing information). Roseville, MN: Ferring Pharmaceuticals; 11/2022.

(7) Policy Update

Date of last review: 1Q2024 Date of next review: 1Q2025

Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

PHP Medi-Cal fecal microbiota, live-jslm (Rebyota $^{\text{TM}}$)

Effective: 01/31/2024 Page 2 of 2