

REBYOTA (fecal microbiota, live - jslm)

Effective Date: 12/01/2023

Date Reviewed: 9/2023, 01/2024

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. LENGTH OF AUTHORIZATION

Coverage will be provided for a one (1) time treatment for one (1) month and may not be renewed.

II. DOSING LIMITS

A. Max Units

- 150 units (1 enema)

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Medical records, chart notes, and/or lab test results documenting the following:

1. Recurrent CDI infection
2. Stool test within 30 days confirming the presence of *C. difficile* toxin or toxigenic *C. difficile*

IV. CRITERIA FOR INITIAL APPROVAL

Prevention of recurrence of Clostridioides difficile infection (CDI)

- A. Member is 18 years of age and older
- B. Medication is prescribed by or in consultation with an infectious disease specialist or gastroenterologist
- C. Member has recurrent CDI infection with either of the following:
 1. Member has had three or more episodes of CDI within the past 12 months (including the most recent episode)
 2. Member has had at least 2 episodes of severe CDI resulting in hospitalization within the past 12 months

- D. Member has a positive stool test for the presence of *C.difficile* toxin or toxigenic *C. difficile* within 30 days prior to treatment
- E. A single, one-time 150 mL dose will be administered rectally 24 to 72 hours after the last dose of at least 10 consecutive days of antibiotics for CDI treatment
- F. Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days)
- G. Member has experienced an inadequate response, intolerance, or contraindication to Zinplava (bezlotoxumab) or fecal microbiota transplantation (FMT) from a reputable source
- H. The request is not for the treatment of CDI.
- I. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

V. RENEWAL CRITERIA

Coverage cannot be renewed.

VI. DOSAGE/ADMINISTRATION

Indication	Dose	Maximum dose (1 billable unit = 1 ml)
Prevention of CDI	Administer a single dose of 150 mL rectally of Rebyota 24 to 72 hours after the last dose of antibiotics for CDI.	150 ml (150 billable units)

VII. INVESTIGATIONAL USE

All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

VIII. BILLING CODE

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS Code	Description
J1440	Fecal microbiota, live - jslm, 1 ml

IX. REFERENCES

1. Rebyota [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc; November 2022.
2. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 updated by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. March 2018;66(7):987-994.
3. Johnson S, Lavergne V, Skinner AM, et al. Clinical practice guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 focused update guidelines on management of Clostridioides difficile infection in Adults. CID 2021; 73 (1 September): e1029-1044.
4. Kelly CR, Fischer M, Allegretti JR, et al. ACG clinical guidelines: Prevention, diagnosis, and treatment of Clostridioides difficile infections. Am J Gastroenterol. 2021; 116: 1124 - 1147.