

Policy Name:	Rebyota (fecal microbiota)	Policy #:	3166P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Rebyota (fecal microbiota, live-jslm).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Rebyota (fecal microbiota, live-jslm) under the specialty medical benefit when the following criteria have been met.

Criteria

1. *Clostridioides difficile* Infection (CDI)

- 1.1 Diagnosis of at least two recurrent (repeating) episodes of CDI refractory (unable to be treated) to standard antibiotic therapy
 - Must be confirmed by positive stool test for *C. difficile* within the past 30 days
- 1.2 Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days)
- 1.3 Age 18 years or older
- 1.4 Prescribed by or in consultation with a gastroenterologist (digestive system doctor) or infectious disease specialist (infection doctor)
- 1.5 Administration will occur 24- 72 hours after completion of antibiotic course

2. Approval Period

- 2.1 Maximum 1 treatment per lifetime

CPT Codes

44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

HCPCS Codes

J1440	Fecal microbiota, live - jslm, 1 ml
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References

1. Rebyota (fecal microbiota, live-jslm) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; November 2022.
2. Orenstein R, Dubberke E, Hardi R, et al. Safety and Durability of RBX2660 (Microbiota Suspension) for Recurrent *Clostridium difficile* Infection: Results of the PUNCH CD Study. *Clin Infect Dis* 2016; 62:596.
3. Khanna S, Assi M, Lee C, et al. Efficacy and Safety of RBX2660 in PUNCH CD3, a Phase III, Randomized, Double-Blind, Placebo-Controlled Trial with a Bayesian Primary Analysis for the Prevention of Recurrent *Clostridioides difficile* Infection. *Drugs*. 2022 Oct;82(15):1527-1538.
4. Orenstein R, Dubberke E, Khanna S, et al. Final Results from a Phase 2b Randomized, Placebo-Controlled Clinical Trial of RBX2660: A Microbiota-Based Drug for the Prevention of Recurrent *Clostridioides difficile* Infection. *Infect Dis Ther*. 2022 Dec 21.
5. Colleen RK, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections. *Am J Gastroenterol*. 2021 Jun 1;116(6):1124-1147.
6. Johnson S, Lavergne, C, 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. *Clin Infect Dis*. 2021 Sep 7;73(5):e1029-e1044.

Created Date: 02/01/23
Effective Date: 02/01/23
Posted to Website: 02/01/23
Revision Date: 02/05/25

DISCLAIMER

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