

<b>Policy Name:</b>	<b>Rebyota (fecal microbiota)</b>	<b>Policy #:</b>	<b>3166P</b>
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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 and Health Alliance Northwest 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 episodes of CDI refractory 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
- 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

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## HCPCS Codes

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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.

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