PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Rebyota (fecal microbiota, live - jslm)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Background statement: Rebyota is a fecal microbiota suspension for rectal administration approved by the FDA in 2022 for the prevention of *Clostridioides difficile* infection (CDI) in patients 18 years and older following completion of antibiotic treatment for recurrent CDI. This is the first FDA-approved microbiota-based therapy for prevention of recurrent CDI. Antibiotics including vancomycin and fidaxomicin are effective at treating CDI, however symptoms recur in ~15% of patients. Preceding FDA approval of Rebyota, Fecal Microbiota Transplantation (FMT) from donor stool administered via colonoscopy was used for prevention of recurrent CDI.

Rebyota (fecal microbiota, live-jslm) will be considered for coverage when the following criteria are met:

Prevention of recurrence of *Clostridioides difficile* infection (CDI)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist; AND
3. Member has documentation of one or more recurrences of CDI (two or more episodes); AND
4. Member has a positive stool test for the presence of *Clostridioides difficile* within the past 30 days; AND
5. Member has completed or will have completed an appropriate antibiotic treatment regimen for recurrent CDI 24-72 hours prior to administration supported by claims history and/or provider documentation; AND
6. Rebyota is not prescribed for the treatment of CDI; AND
7. **Dosage allowed/Quantity limit**:
   Administer a single dose of 150 mL rectally 24-72 hours after the last dose of antibiotics for CDI.

If all the above requirements are met, one dose of the medication will be approved.

For **reauthorization**:
1. Medication will not be reauthorized.

CareSource considers Rebyota (fecal microbiota, live-jslm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/30/2023	New policy for Rebyota created.

References:

1. Rebyota. Package Insert. Ferring Pharmaceuticals Inc.; 2022. Accessed January 30, 2023.
2. Rebyota. Prescribing information. Parsippany, NJ: Ferring Pharmaceuticals Inc; 2022.
3. McDonald LC, Gerding DN, Johnson S, Bakken JS, Carroll KC, Coffin SE, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018 Feb 15;66(7):1-48. https://doi.org/10.1093/cid/cix1085
4. Khanna S, Assi M, Lee C, Yoho D, Louie T, Knapple W, 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):1527-38. https://doi.org/10.1007/s40265-022-01797-x.
5. Orenstein R. The Role of Microbiome-Based Therapeutics in Clostridioides difficile Infection: Durable, Long-Term Results of RBX2660. Infect Dis Ther. 2023;12(1):1-7. doi:10.1007/s40121-022-00714-9
6. Orenstein R, Dubberke ER, Khanna S, et al. Durable reduction of Clostridioides difficile infection recurrence and microbiome restoration after treatment with RBX2660: results from an open-label phase 2 clinical trial. BMC Infect Dis. 2022;22(1):245. Published 2022 Mar 12. doi:10.1186/s12879-022-07256-y.
7. Dubberke ER, Lee CH, Orenstein R, Khanna S, Hecht G, Gerding DN. Results from a randomized, placebo-controlled clinical trial of a RBX2660-a microbiota-based drug for the prevention of recurrent Clostridium difficile infection. Clin Infect Dis. 2018;67(8):1198-1204. doi:10.1093/cid/ciy259.

Effective date: 07/01/2023
Revised date: 01/30/2023