Medical Drug Clinical Criteria

Subject:	Rebyota (fecal microbiota, live – jslm)		
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Overview

This document addresses the use of Rebyota (fecal microbiota, live – jslm), approved by the Food and Drug Administration (FDA) for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Rebyota is administered as a single dose rectal enema within 24 to 72 hours after completion of antibiotic therapy. Rebyota is not indicated for treatment of CDI.

The Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) published a 2021 focused update to their 2017 CDI management guidelines. Recommendations for the treatment of an initial episode of CDI in adults include Dificid as the preferred option with oral vancomycin as an alternative. Recommendations for CDI first recurrence include Dificid in a standard or extended-pulse regimen as the preferred option with standard or tapered/pulsed vancomycin as an alternative. For individuals with a recurrent CDI episode within the last 6 months, IDSA/SHEA recommends using Zinplava with standard of care antibiotics. Recommendations for CDI second or subsequent recurrence include Dificid in a standard or extended-pulse regimen, tapered/pulsed vancomycin, vancomycin followed by Xifaxan, or fecal microbiota transplant.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Rebyota (fecal microbiota, live – jslm)

Requests for Rebyota (fecal microbiota, live – jslm) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is requesting Rebyota for prevention of recurrence of *Clostridiodes difficile* infection; **AND**
III. Individual has had at least three episodes of *Clostridiodes difficile* infection (initial episode and two recurrences) treated with antibiotic therapy (including Dificid, metronidazole or oral vancomycin) (IDSA/SHEA 2021); **AND**
IV. Current episode of *Clostridiodes difficile* infection has been verified with a positive stool test for *Clostridiodes difficile* toxin; **AND**
V. Rebyota will be administered within 24 to 72 hours of completing antibiotic treatment for the current *Clostridiodes difficile* infection episode.

Requests for Rebyota (fecal microbiota, live – jslm) may not be approved for the following:

I. Treatment of *Clostridiodes difficile* infection; **OR**
II. Use in combination with Vowst or Zinplava during the same *Clostridiodes difficile* infection episode; **OR**
III. May not be approved when the above criteria are not met and for all other indications.

Approval Duration: One dose

Quantity Limits

Rebyota (fecal microbiota, live – jslm) Quantity Limit

Drug	Limit
Rebyota (fecal microbiota, live – jslm) 150 mL rectal suspension	One 150 mL dose, one time

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1440	Fecal microbiota, live - jslm, 1 ml [Rebyota]

ICD-10 Diagnosis

A04.71	Enterocolitis due to Clostridium difficile, recurrent

Document History

Reviewed: 9/8/2025
Document History:

- 9/8/2025 – Annual Review: No changes. Coding Reviewed: No changes.
- 9/9/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 9/11/2023 – Annual Review: Add age criteria; add Vowst to may not approve combination therapy criteria. Coding Reviewed: No changes.
- 2/24/2023 – Select Review: New clinical criteria and quantity limit for Rebyota. Coding Reviewed: Added HCPCS J3490, J3590, C9399. All diagnoses pend. Effective 7/1/2023 Added HCPCS J1440. Added ICD-10-CM A04.71. Deleted HCPCS J3490, J3590, C9399.

References

1. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
2. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guidelines 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;73(5):1029-1044.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Rebyota (fecal microbiota, live - jslm) suspension for rectal use. Roseville, MN: Ferring Pharmaceuticals. November 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.