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# 5.50.034

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	October 1, 2023
<b>Subsection:</b>	Gastrointestinal Agents	<b>Original Policy Date:</b>	January 13, 2023
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**Last Review Date:** September 8, 2023

## Rebyota

### Description

Rebyota (fecal microbiota, live-jslm)

### Background

Rebyota (fecal microbiota, live-jslm) is an opaque fecal microbiota suspension for rectal administration. Rebyota is manufactured from human fecal matter sourced from qualified donors (1).

### Regulatory Status

FDA-approved indication: Rebyota is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI (1).

The safety and effectiveness of Rebyota have not been established in pediatric patients (1).

### Related policies

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### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Rebyota may be considered **medically necessary** if the conditions indicated below are met.

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Rebyota may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Recurrent *Clostridioides difficile* infection (CDI)

**AND ALL** of the following:

- Positive stool test for *C. difficile* toxin or toxigenic *C. difficile*
- Used for the prevention of CDI
- Patient has completed 10 consecutive days of antibiotic therapy
- CDI is under control (<3 unformed/loose stools/day for 2 consecutive days)
- Administered 24 to 72 hours following the last dose of antibiotic treatment for CDI

## Prior – Approval *Renewal* Requirements

Same as above

### [Policy Guidelines](#)

## Pre - PA Allowance

None

## Prior – Approval Limits

**Quantity** 1 carton (1 bag containing Rebyota and 1 administration set)

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

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## Rationale

### Summary

Rebyota is indicated for the prevention of recurrent CDI in adults following antibiotic treatment for recurrent CDI. The safety and effectiveness of Rebyota have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Rebyota while maintaining optimal therapeutic outcomes.

### References

1. Rebyota [package insert]. Roseville, MN: Ferring Pharmaceuticals; November 2022.

## Policy History

Date	Action
January 2023	Addition to PA
March 2023	Annual review
June 2023	Annual review
September 2023	Annual review

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.**