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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	January 13, 2023
Subject:	Rebyota	**Page:**	1 of 3

Last Review Date: June 13, 2024

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.

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:

a. Positive stool test for *C. difficile* toxin or toxigenic *C. difficile*
b. Used for the prevention of CDI
c. Patient has completed 10 consecutive days of antibiotic therapy
d. CDI is under control (<3 unformed/loose stools/day for 2 consecutive days)
e. 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

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
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.