



MVP Health Care Medical Policy

Medicare Part B: C. Difficile Drug Therapy

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2024
Approval Date: 07/01/2025
Effective Date: 09/01/2025
Related Policies: Zinplava (bezlotoxumab)

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

Rebyota (Fecal Microbiota, Live, suspension)

Overview/Summary of Evidence

Fecal microbiota, live is a bacterial spore suspension in capsules for oral administration and a rectal microbiota suspension indicated for the prevention of recurrence of *C. difficile* infection (CDI) after antibiotic treatment for recurrent CDI (rCDI). Recurrence of CDI is defined as a relapse of CDI symptoms within 2 - 8 weeks of successful treatment of the initial episode. It is not indicated for the treatment of CDI. Fecal microbiota, live is manufactured from human fecal matter sourced from qualified donors. Rectal fecal microbiota, live is administered 24 to 72 hours after the conclusion of antibiotic treatment for CDI with oral antibiotics being avoided for up to 8 weeks after use. Oral fecal microbiota, live is administered 48 to 96 hours after the conclusion of antibiotic treatment for CDI with antibiotics to be avoided during use.

Indications/Criteria

Rebyota may be considered for coverage when:

- Member has a diagnosis of recurrent C. difficile infection (rCDI) defined as **either**:
 - Had at least 2 episodes of severe CDI resulting in hospitalization within the last year OR
 - At least one recurrence after a primary episode and had completed at least 1 round of standard-of-care oral antibiotic (SOC) therapy (e.g., vancomycin, fidaxomicin)
- Documentation of a positive C.difficile stool sample
- Chart notes or claims history shows standard of care antibacterial therapy (i.e. vancomycin, fidaxomicin) for the primary episode and presenting rCDI
- Prescriber confirmation that Rebyota is being used for secondary C. difficile infection **prophylaxis** after antibiotic treatment for recurrent C. difficile infection (rCDI)
- Prescriber confirmation that antibacterial treatment for recurrent CDI is completed 24 to 72 hours prior to starting Rebyota
- Quantity limit per episode:
 - Rebyota: 150ml as a single dose

Initial approval of 150ml per episode within 2 months

Subsequent approval for a new episode of rCDI will be reviewed on a case by cases basis and must include documentation of previous response and clinical benefit.

Maximum of a one-time repeat dose

Members may step through Part D drugs prior to obtaining approval for Rebyota. Please refer to the MVP website for the Medicare Part D formulary for a full list of covered drugs.

Exclusions

The use of Rebyota will not be covered for the following situations:

- Treatment of CDI
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

References

1. Rebyota (fecal microbiota, live). Clinical Pharmacology. Revised April 27, 2023. Accessed May 30, 2023. [9009000002 REBYOTA-PI 11-2022.pdf \(ferringusa.com\)](#)

2. Vowst. Prescribing Information. Seres Therapeutics, Inc. Cambridge, MA. Revised April 2023. [Microsoft Word - Final-VOWST-PI labeling-text-26April23 \(serestherapeutics.com\)](#)
3. Centers for Disease Control and Prevention. C.dff (clostridioides difficile). FAQs for Clinicians about D.Diff. [FAQs for Clinicians about C. diff | CDC](#). October 25, 2022. Accessed on June 5, 2023
4. [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 \(SHEA\) - PMC \(nih.gov\)](#)
5. Study Details | ECOSPOR III - SER-109 Versus Placebo in the Treatment of Adults With Recurrent Clostridium Difficile Infection | ClinicalTrials.gov
6. AGA Clinical Practice Guideline on Fecal Microbiota–Based Therapies for Select Gastrointestinal Diseases - Gastroenterology (gastrojournal.org)
7. Rebyota. Prescribing Information. Roseville, MN: Ferring Pharmaceuticals.. Revised November 2022.