MVP Health Care Medical Policy

Medicare Part B: C. Difficile Drug Therapy

Type of Policy: **Drug Therapy**
Prior Approval Date: **NA**
Approval Date: **11/01/2024**
Effective Date: **01/01/2024**
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. 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 (CDI) defined as **either**:

    - Had at least 2 episodes of severe CDI resulting in hospitalization within the last year
    - At least one recurrence after a primary episode and had completed at least 1 round of standard-of-care oral antibiotic 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
- Prescriber confirmation that Rebyota is being used for secondary C. difficile infection **prophylaxis** after antibiotic treatment for recurrent C. difficile infection (CDI).
- Prescriber confirmation that antibacterial treatment for recurrent CDI is completed 24 to 72 hours prior to starting Rebyota.
- Quantity limit per episode: 150ml as a single dose

Initial approval of 150ml per episode within 2 months
Subsequent approval for a new episode of CDI requires documentation of previous response and clinical benefit

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
- Dosing, age, and/or frequency outside of the FDA approved package labeling

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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)