Reference number(s)
5693-A

STANDARD MEDICARE PART B MANAGEMENT

REBYOTA (fecal microbiota, live - jslm)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

Limitations of Use
Rebyota is not indicated for the treatment of CDI.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Medical records, chart notes, and/or lab test results documenting the following:
   1. Recurrent CDI infection
   2. Stool test confirming the presence of toxigenic *C. difficile*

III. EXCLUSIONS

Coverage will not be provided for members requesting Rebyota for the treatment of CDI.

IV. CRITERIA FOR INITIAL APPROVAL

Prevention of recurrence of Clostridioides difficile infection (CDI)
Authorization of 30 days for a one-time treatment may be granted for prevention of CDI when all of the following criteria are met:
   A. Member is 18 years of age and older
   B. Member has recurrent CDI infection including either of the following:
      1. At least one recurrence after a primary episode and had completed at least 1 round of standard-of-care oral antibiotic therapy (e.g., metronidazole, vancomycin)
      2. Had at least 2 episodes of severe CDI resulting in hospitalization within the last year

C. Member has a positive stool test for the presence of toxigenic *C. difficile* within 30 days prior to treatment
D. A single, one-time 150 mL dose will be administered rectally 24 to 72 hours after the last dose of antibiotics

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Rebyota.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Rebyota are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Rebyota [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc; November 2022.