CVS Caremark®

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| Reference number(s) |
| 5692-A |

# Specialty Guideline Management Rebyota

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Rebyota | fecal microbiota, live - jslm |

## 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 Indications1

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 Use1

Rebyota is not indicated for the treatment of CDI.

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

* Medical records, chart notes, and/or lab test results documenting the following:
  + Recurrent CDI
  + Stool test confirming the presence of C.difficile toxin or toxigenic C. difficile

## Exclusions

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

## Coverage Criteria

### Prevention of Recurrence of Clostridioides Difficile Infection (CDI)1

Authorization of 30 days for a one-time treatment may be granted for prevention of CDI when all of the following criteria are met:

* Member is 18 years of age and older
* Member has recurrent CDI including either of the following:
  + At least one recurrence after a primary episode and has completed at least 1 round of standard-of-care oral antibiotic therapy (e.g., metronidazole, fidaxomicin)
  + Has had at least 2 episodes of severe CDI resulting in hospitalization within the last year
* Member has a positive stool test for the presence of C.difficile toxin or toxigenic C. difficile within 30 days prior to treatment
* A single, one-time 150 mL dose will be administered rectally 24 to 72 hours after the last dose of antibiotics

## References

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