STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA	48488		GPI-10 (5252201030)	

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Rebyota?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin]) for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of first dose of Rebyota AND a positive stool test for *C. difficile*
   - The patient has not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:
   A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
   B. You are 18 years of age or older
   (Denial text continued on next page)

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FECAL MICROBIOTA SUSPENSION

GUIDELINES FOR USE (CONTINUED)

C. **If you have NOT previously received Rebyota, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior

D. **If you have been previously treated with Rebyota, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Rebyota AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebyota.

REFERENCES

- Rebyota [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
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Client Approval: 05/23
P&T Approval: 01/23