PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Rebyota (fecal microbiota, live - jslm)</th>
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</thead>
<tbody>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
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Background statement: Rebyota is a fecal microbiota suspension for rectal administration approved by the FDA in 2022 for the prevention of *Clostridioides difficile* infection (CDI) in patients 18 years and older following completion of antibiotic treatment for recurrent CDI. This is the first FDA-approved microbiota-based therapy for prevention of recurrent CDI. Antibiotics including vancomycin and fidaxomicin are effective at treating CDI, however symptoms recur in ~15% of patients. Preceding FDA approval of Rebyota, Fecal Microbiota Transplantation (FMT) from donor stool administered via colonoscopy was used for prevention of recurrent CDI.

Rebyota (fecal microbiota, live-jslm) will be considered for coverage when the following criteria are met:

**Prevention of recurrence of Clostridioides difficile infection (CDI)**

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist; AND
3. Member has documentation of one or more recurrences of CDI (two or more episodes); AND
4. Member has a positive stool test for the presence of *Clostridioides difficile* within the past 30 days; AND
5. Member has had a trial and failure of Zinplava; AND
6. Member has completed or will have completed an appropriate antibiotic treatment regimen for recurrent CDI 24-72 hours prior to administration supported by claims history and/or provider documentation; AND
7. Rebyota is not prescribed for the treatment of CDI; AND
8. **Dosage allowed/Quantity limit:**
   - Administer a single dose of 150 mL rectally 24-72 hours after the last dose of antibiotics for CDI.

*If all the above requirements are met, one dose of the medication will be approved.*

For **reauthorization**:
1. Medication will not be reauthorized.

CareSource considers Rebyota (fecal microbiota, live-jslm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

OH-MED-P-366685
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<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>01/30/2023</td>
<td>New policy for Rebyota created.</td>
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<tr>
<td>07/13/2023</td>
<td>Added trial of Zinplava.</td>
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References:


Effective date: 01/01/2024
Revised date: 01/30/2023