Rebyota (fecal microbiota, live - jslm)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Clostridioides difficile infection (CDI) is a potentially life-threatening gastrointestinal condition caused by toxin-producing *C. difficile* bacteria. CDI commonly occurs after antibiotic use disrupts the normal gut microbiota. Recurrent CDI is a significant clinical challenge, with approximately 20-30% of individuals experiencing at least one recurrence after initial treatment. The risk of additional recurrences increases with each episode.

Standard treatment for CDI includes antibiotics such as vancomycin, fidaxomicin, or metronidazole. For recurrent CDI, extended antibiotic regimens, fecal microbiota transplantation (FMT), or bezlotoxumab (an anti-toxin monoclonal antibody) may be used.

Rebyota (fecal microbiota, live - jslm) is a microbiome-based therapy approved for the prevention of recurrent CDI in adults. It is administered as a single 150 mL rectal dose containing live microorganisms derived from human fecal matter. Rebyota aims to restore the diversity and function of the gut microbiome to prevent CDI recurrence.

Definitions

"Clostridioides difficile infection (CDI)" refers to a symptomatic infection due to toxin-producing C. difficile bacteria, typically characterized by diarrhea.

"Fecal microbiota transplantation (FMT)" refers to the transfer of fecal material containing microbiota from a healthy donor into a recipient's gastrointestinal tract to restore microbial diversity.

"Recurrent CDI" is defined as an episode of CDI that occurs within 8 weeks after the onset of a previous episode, provided symptoms from the previous episode have resolved.

Medical Necessity Criteria for Initial Authorization

The Plan considers Rebyota (fecal microbiota, live - jslm) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an infectious disease specialist or gastroenterologist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of recurrent *Clostridioides difficile* infection (CDI), characterized by EITHER of the following:
    a. at least 3 total episodes (second recurrence) of CDI in the past-12 months; *or*
    b. at least 2 episodes of severe CDI resulting in hospitalization within the last 12-months; *AND*
4. Recent (within the last 60-days) documentation indicating of ALL of the following:
    a. Presence of diarrhea, defined as passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days; *and*
    b. Positive stool test for *C. difficile* toxin or toxigenic *C. difficile*; *and*
    c. The member has completed or will have completed at least 10 consecutive days of standard-of-care antibiotic therapy (e.g., vancomycin, fidaxomicin) for treatment of CDI;*and*
    d. CDI symptoms are currently under control, defined as <3 unformed/loose stools per day for 2 consecutive days; *and*
    e. Rebyota (fecal microbiota, live - jslm) is being used for the prevention of recurrence of CDI (i.e., NOT for the treatment of CDI); *and*
    f. Rebyota (fecal microbiota, live - jslm) will be administered 24-72 hours after completion of antibiotic therapy for CDI; *AND*
5. Rebyota (fecal microbiota, live - jslm) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    - A single 150 mL dose administered rectally

If the above prior authorization criteria are met, the requested product will be authorized for a single 150 mL dose (i.e., one-time approval).

Medical Necessity Criteria for Reauthorization

The Plan does not authorize reauthorization or repeat courses of Rebyota (fecal microbiota, live - jslm).

- Rebyota is indicated as a one-time, single-dose treatment for the prevention of recurrent *Clostridioides difficile* infection (CDI).
- The FDA-approved labeling does not provide guidance on repeat administration or extended use beyond the initial single dose.
- Clinical trials supporting the efficacy and safety of Rebyota identified benefits with a single dose administration.
- There is currently insufficient evidence to support the safety or efficacy of repeated doses of Rebyota.
- Any consideration for use beyond the initial approved course would be subject to individual case review based on clinical circumstances and emerging evidence.

Experimental or Investigational / Not Medically Necessary

Rebyota (fecal microbiota, live - jslm) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Administration of multiple doses of Rebyota.
- Prophylactic use in those without a history of CDI.
- Treatment of active CDI (Rebyota is only approved for prevention of recurrence).
- Use for prevention or treatment of conditions other than CDI (e.g., inflammatory bowel disease, irritable bowel syndrome).
- Use in combination with other microbiome-based therapies.
- Use in members under 18 years of age.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract

G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen
J1440	Fecal microbiota, live - jslm, 1 ml
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent
Z86.19	Personal history of other infectious and parasitic diseases

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Clinical Guideline Revision / History Information

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