Vowst (fecal microbiota spores, live-brpk)

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 or fidaxomicin. For recurrent CDI, extended antibiotic regimens, fecal microbiota transplantation (FMT), or bezlotoxumab (an anti-toxin monoclonal antibody) may be used.

Vowst (fecal microbiota spores, live-brpk) is an oral microbiome-based therapy approved for the prevention of recurrent CDI in adults. It contains live bacterial spores derived from human fecal matter and is administered as a 3-day course of oral capsules (4 capsules per dose). While the mechanism of action is not entirely known, it is proposed that Vowst (fecal microbiota spores, live-brpk) helps 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 the occurrence of CDI within 8 weeks following the onset of a previous episode, provided the symptoms from the previous episode resolved with appropriate treatment.

Medical Necessity Criteria for Initial Authorization

The Plan considers Vowst (fecal microbiota spores, live-brpk) 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 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. The member is unable to use, or has tried and failed Rebyota (fecal microbiota, live-jslm); *AND*
5. 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*
    a. Vowst is being used for the prevention of recurrence of CDI (i.e., NOT for the treatment of CDI); *and*
    e. Vowst will be initiated 2-4 days after completion of antibiotic therapy for CDI; *AND*
6. Vowst (fecal microbiota spores, live-brpk) 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.
    - *12 capsules per 3-day treatment course*

If the above prior authorization criteria are met, the requested product will be authorized for a one-time 3-day treatment course.

Medical Necessity Criteria for Reauthorization

The Plan does not authorize reauthorization or repeat courses of Vowst (fecal microbiota spores, live-brpk).

- Vowst (fecal microbiota spores, live-brpk) is indicated as a one-time, 3-day treatment course 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 3-day course.
- Clinical trials supporting the efficacy and safety of Vowst evaluated only a single 3-day course of treatment. Open-label studies have assessed the safety and tolerability (but not efficacy or effectiveness) of an additional dose of Vowst (fecal microbiota spores, live-brpk) administered at least 8 weeks after the first treatment course in a small cohort of individuals with recurrent CDI. However, this has not been studied in a randomized, controlled trial environment and more data is required.
- There is currently insufficient evidence to support the safety or efficacy of repeated courses of Vowst (fecal microbiota spores, live-brpk).
- 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

Vowst (fecal microbiota spores, live-brpk) 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 courses of Vowst (beyond the initial 3-day course).
- Prophylactic use in members without a history of CDI.
- Treatment of active CDI (Vowst 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.

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