Pharmacy Medical Necessity Guidelines:
Vowst (fecal microbiota spores, live-brpk)

Effective: August 11, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Vowst (fecal microbiota spores, live-brpk) is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in patients 18 years of age or older following antibacterial treatment for recurrent CDI. Vowst is not indicated for the treatment of CDI.

Prior to administering Vowst, antibacterial treatment should be completed for recurrent CDI for two to four days. The patient should drink 296 mL of magnesium citrate on the day before and at least eight hours prior to taking the first dose of Vowst (in clinical trials, patients with impaired kidney function received polyethylene glycol electrolyte solution, although that product is not approved for this use).

The dosage of Vowst is four capsules taken orally once daily for three consecutive days. Each dose of four capsules should be taken on an empty stomach prior to the first meal of the day.

COVERAGE GUIDELINES

The plan may authorize coverage of Vowst (fecal microbiota spores, live-brpk) for Members when **ALL** of the following criteria for a particular regimen are met and limitations do not apply:

1. Documentation the Member has had three or more episodes of *Clostridioides difficile* infection in the previous twelve months

AND

2. The Member is 18 years of age or older

AND

3. Documentation that Vowst is prescribed by or in consultation with a specialist (e.g., infectious disease, gastroenterologist)

AND

4. Member had a recent episode of recurrent *C. difficile* infection with documentation of ALL of the following:
    a. Member had no more than two unformed stools for two consecutive days

    AND

    b. *C. difficile* infection has been treated with an antibiotic within the past five days of requesting prior authorization for Vowst

    AND

    c. The most recent treatment for *C. difficile* was with one of the following antibiotics: vancomycin or fidaxomicin

LIMITATIONS

1. Vowst will be limited to 12 capsules per treatment course.
2. Approval duration of Vowst will be limited to one month.

CODES

None

REFERENCES

1. Kelly CP, Lamont JT, Bakken JS. *Clostridioides difficile* infection in adults: treatment and prevention. UpToDate. Available at: www.uptodate.com. Accessed: 26 July 2023.

2. Kelly CR, Fischer M, Allegretti JR, et al. American College of Gastroenterology (ACG) Clinical guidelines: prevention, diagnosis, and treatment of *Clostridioides difficile* infections. *Am J Gastroenterol*. 2021;116:1124-1147.
3. Vowst (fecal microbiota spores, live-brpk) [prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc.; April 2023.

APPROVAL HISTORY

August 8, 2023: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 13, 2024: Administrative change to fax number.
- August 12, 2025: No changes
- August 11, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.