Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: August 12, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – 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.

Clinical Guideline Coverage Criteria

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. Patient had a recent episode of recurrent C diff with documentation of all the following:
   - **a)** Patient had no more than 2 unformed stools for 2 consecutive days
   - **b)** *C. difficile* infection has been treated with an antibiotic within the past 5 days of requesting the PA for Vowst
   - **c)** Most recent treatment 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.; February 2025.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- August 13, 2024: No changes.
- August 12, 2025: 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 popula tion 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.