Vowst (fecal microbiota spores, live-brpk)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Vowst is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

Limitations of Use
Vowst is not indicated for the treatment of CDI.

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Medical records, chart notes, and/or lab test results documenting the following:
    a. Recurrent CDI
    b. Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile*

Exclusions
Coverage will not be provided for members requesting Vowst for the treatment of CDI.

Criteria for Initial Approval

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

Authorization of 30 days for a one-time treatment may be granted for prevention of CDI when all of the following criteria are met:

A. Member is 18 years of age and older
B. Member has had three or more episodes of CDI within the past 12 months (including the most recent episode).
C. Member has a recent episode of recurrent CDI with all of the following:
    a. At least 3 unformed stools per day for 2 consecutive days
    b. Stool test confirming the presence of *C. difficile* toxin or toxigenic *C. difficile*
    c. An adequate clinical response (e.g., resolution of symptoms) following standard of care antibiotic therapy (e.g., vancomycin, fidaxomicin)

Vowst (fecal microbiota spores, live-brpk) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Coverage will not be provided for members requesting Vowst for the treatment of CDI.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Vowst capsules – 1 bottle (12 capsules) per lifetime

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Vowst [package insert]. Cambridge, MA: Seres Therapeutics Inc; June 2024.

POLICY HISTORY

Policy #: 05.05.07
Original Effective Date: July 17, 2023
Reviewed: October 2025
Revised:
Current Effective Date: July 17, 2023