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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	June 2, 2023
Subject:	Vowst	**Page:**	1 of 3

Last Review Date: September 8, 2023

Vowst

Description

Vowst (fecal microbiota, live-brpk)

Background
Vowst (fecal microbiota, live-brpk) is a bacterial spore suspension in capsules for oral administration. Vowst is manufactured from human fecal matter sourced from qualified donors (1).

Regulatory Status
FDA-approved indication: Vowst is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI (1).

Limitation of Use:
Vowst is not indicated for treatment of CDI.

The safety and effectiveness of Vowst have not been established in pediatric patients (1).

Related policies
Rebyota

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vowst may be considered **medically necessary** if the conditions indicated below are met.

Vowst may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Recurrent *Clostridioides difficile* infection (CDI)

AND ALL of the following:

a. Positive stool test for *C. difficile* toxin or toxigenic *C. difficile*
b. Used for the prevention of CDI
c. Patient has completed 10 consecutive days of antibiotic therapy with fidaxomicin or vancomycin
d. CDI is under control (<3 unformed/loose stools per day for 2 consecutive days)
e. Administered 48 to 96 hours following the last dose of antibiotic treatment for CDI

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior – Approval Limits

Quantity 12 capsules

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vowst is indicated for the prevention of recurrent CDI in adults following antibiotic treatment for recurrent CDI. The safety and effectiveness of Vowst have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Vowst while maintaining optimal therapeutic outcomes.

References

1. Vowst [package insert]. Cambridge, MA: Seres Therapeutics, Inc.; April 2023.

Policy History

Date	Action
June 2023	Addition to PA
September 2023	Annual review. Per SME, revised antibiotic therapy requirement to indicate vancomycin or fidaxomicin specifically

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.