CVS Caremark®

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| Reference number(s) |
| 5922-A |

# Specialty Guideline Management Vowst

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Vowst | (fecal microbiota spores, live-brpk) |

## Indication

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indication1

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 Use1

Vowst is not indicated for the treatment of CDI.

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

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

* Medical records, chart notes, and/or lab test results documenting the following:
  + Recurrent CDI
  + 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.

## Coverage Criteria

### Prevention of recurrence of Clostridioides difficile infection (CDI)1

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

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

## References

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