

PHARMACY COVERAGE GUIDELINE

VOWST™ (fecal microbiota spores, live-brpk) oral Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for VOWST (fecal microbiota spores, live-brpk)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Gastroenterologist or Infectious Disease Specialist, or in consultation with one

Indication

- Clostridioides difficile infection (CDI) for prevention of recurrence following standard of care antibacterial treatment for recurrent CDI

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Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Documented CDI episodes with diarrhea (3 or more unformed stools per day for at least 2 consecutive days)
- Positive Clostridioides difficile stool sample using a toxin assay
- History of 3 or more CDI episodes (initial plus 2 recurrences) treated with antibiotic therapy within 12 months
- At least **ONE** of the following risk factors for recurrent CDI:
 - Greater than 65 years of age
 - Immunocompromised (e.g., active hematologic malignancy, use of antineoplastic or immunomodulating agent, corticosteroids, solid organ transplant, asplenia, immunodeficiency condition)
 - Clinically severe CDI
 - Infection due to hypervirulent Clostridioides difficile strains (ribotypes 027, 078, or 244)
- Completion of standard of care antibacterial treatment for CDI with symptom resolution (less than 3 unformed stools in 24 hours for 2 or more consecutive days)
- Vowst treatment will begin 2 to 4 days after the end of standard of care antibacterial treatment
- Will not be used for treatment of CDI

Safety

- No concomitant use with other fecal transplants or preventative measures (e.g., Rebyota (fecal microbiota, live jsIm), Zinplava (bezlotoxumab injection))
- Does not have any of the following:
 - Neutropenia (absolute neutrophil count less than 500 cells/mm³)
 - History of fecal microbiota transplantation
 - Use of antibacterial therapy other than standard of care for most recent CDI episode
 - Toxic megacolon
 - Small bowel ileus
 - History of irritable bowel syndrome
 - History of active inflammatory bowel disease (ulcerative colitis, Crohn's disease, microscopic colitis) with diarrhea caused by active inflammatory bowel disease in past 12 months
 - Major gastrointestinal surgery (e.g., significant bowel resection or diversion) within previous three months or any history of total colectomy or bariatric surgery

Alternative Therapies

- Failure, contraindication, intolerance, or not a candidate for Rebyota (fecal microbiota, live jsIm)

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Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Documentation Requirements

- A completed request form must be submitted, including:
 - Chart notes
 - Lab results
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration:

- One dose (four capsules) orally, once daily for three consecutive days
 - One fill of 12 capsules in a six month period
 - OR end of plan year
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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
 2. Off-Label Use of Cancer Medications
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Description:

VOWST (fecal microbiota spores, live-brpk) 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). VOWST is not indicated for treatment of CDI.

Clostridioides (formerly *Clostridium*) *difficile* (*C. difficile*) infection is a bacterium causing symptoms ranging from diarrhea to more serious intestinal conditions such as colitis. CDI is one of the most common hospital-acquired infections and is an increasingly frequent cause of morbidity and mortality among older adult hospitalized individuals. *C. difficile* colonizes the human intestinal tract after the normal gut flora has been altered by antibiotic therapy and is the causative organism of antibiotic-associated pseudomembranous colitis.

Clinical symptoms vary widely, from asymptomatic colonization to pseudomembranous colitis with bloody diarrhea, fever, severe abdominal pain, toxic megacolon, sepsis, bowel perforation and death. *C. difficile* infection is defined by the presence of symptoms, usually diarrhea, and either a stool test positive for *C. difficile* toxins (toxigenic *C. difficile*) or colonoscopic or histopathologic findings revealing pseudomembranous colitis.

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The incidence of recurrent *Clostridium difficile* infection is reported to be 5-30% (mean 20%) of patients, usually within the first eight weeks after treatment of the infection.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Clostridioides (formerly Clostridium) difficile (C. difficile) infection (CDI):

A bacterium causing symptoms ranging from diarrhea to more serious intestinal conditions such as colitis. CDI is one of the most common hospital-acquired infections and is an increasingly frequent cause of morbidity and mortality among older adult hospitalized individuals. *C. difficile* colonizes the human intestinal tract after the normal gut flora has been altered by antibiotic therapy and is the causative organism of antibiotic-associated pseudomembranous colitis.

Clinical cure:

Cure of the baseline episode of *Clostridium difficile* infection after a standard-of-care (SOC) antimicrobial regimen with no reported diarrhea (≤ 2 loose stools per 24 hours) on the 2 days immediately following the last day of SOC treatment

CDI recurrence:

The development of a new episode of diarrhea associated with a positive stool test for *Clostridioides difficile (C. difficile)* toxin following clinical cure of the initial CDI episode. Recurrent CDI is defined by resolution of CDI symptoms while on appropriate therapy, followed by reappearance of symptoms within two months of discontinuing treatment. Recurrence can represent either relapse or reinfection. Relapse is a recurrence with the original isolate. Reinfection is a recurrence with a new isolate.

Risk factors for recurrent CDAD/CDI:

- Individual is 65 years of age or older
- Episode is described as clinically severe CDAD/CDI
- Infection is due to hypervirulent strains of Clostridioides difficile (ribotypes 027, 078 or 244)
- Individual is immunocompromised (e.g., active hematologic malignancy, uses an antineoplastic or immunomodulating agent, uses corticosteroids, has received a solid organ transplant, is asplenic, or has an immunodeficiency condition, etc.)

Per Vowst package insert:

	CDI Recurrence		Difference from Placebo
	VOWST	Placebo	
After treatment			
Through 8 weeks	12.4%	39.8%	27.4%
Through 12 weeks	18.0%	46.2%	28.2%
Through 24 weeks	21.3%	47.3%	26.0%

***C. difficile* treatment failure:**

Failure of treatment is not defined by development of a recurrent episode. Treatment failure is an inadequate response with unresolved *C. difficile* infection.

ORIGINAL EFFECTIVE DATE: 08/17/2023 | ARCHIVE DATE: | LAST REVIEW DATE: 08/21/2025 | LAST CRITERIA REVISION DATE: 08/21/2025

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Resources:

Vowst (fecal microbiota spores, live-brpk) capsule product information, revised by Aimmune Therapeutics, Inc. 02-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2025.

Borody TJ, Ramrakha S. Fecal microbiota transplantation for treatment of *Clostridioides difficile* infection. In: UpToDate, Lamont JT, Meyer C, Bogorodskaya M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through April 2025. Topic last updated March 21, 2025. Accessed May 29, 2025.

Kelly CP, Lamont JT, Bakken JS. *Clostridioides difficile* infection in adults: Treatment and prevention. In: UpToDate, Calderwood SB, Bogorodskaya M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through April 2025. Topic last updated May 21, 2025. Accessed May 29, 2025.

Johnson S, Lavergne V, Skinner AM, et al.: Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults. CID 2021;73 (1 September): e1029. Accessed June 01, 2023. Re-evaluated July 20, 2024.

Feuerstadt P, Louie TJ, Lashner B, et al: SER-109, an Oral Microbiome Therapy for Recurrent *Clostridioides difficile* Infection. NEJM 2022 Jan 20;386 (3):220-229. Accessed May 17, 2023. Re-evaluated July 02, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03183128: A Phase 3 Multicenter, Randomized, Double Blind, Placebo Controlled, Parallel Group Study to Evaluate the Safety, Tolerability, & Efficacy of SER-109 vs. Placebo to Reduce Recurrence of *Clostridium Difficile Infection* (CDI) in Adults. Available from: <http://clinicaltrials.gov>. Last update posted April 27, 2023. Last verified June 2021. Accessed May 17, 2023. Re-evaluated July 20, 2024.