**VOWST™ (fecal microbiota spores, live-brpk) capsules**

**SAMPLE LETTER OF MEDICAL NECESSITY**

Some payers may require that a prescriber documents a patient’s medical necessity for treatment to get insurance coverage for a pharmaceutical product. The following letter is for informational purposes and only intended as a sample letter of medical necessity for VOWST to illustrate the types of information a payer may request. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient’s health plan before completing a letter of medical necessity. The decision to prescribe VOWST as well as submit any letter of medical necessity on behalf of an individual patient and the contents thereof are the sole responsibility of the treating physician. Use of this letter is not a substitute for the professional medical judgement of the treating physician and does not guarantee coverage for the product.

The prescriber should refer to the VOWST full [Prescribing Information](https://www.serestherapeutics.com/our-products/VOWST_PI.pdf) when determining whether the product is medically appropriate for a patient.

**Considerations to include in relevant patient medical history**

* **Important note:** Request if payer will consider an expedited review so that your patient does not miss the VOWST treatment window and delay treatment
* Chart notes1,2
	+ Risk factors for recurrence
		- Age 65 years or older
		- Immunocompromised
		- History of *Clostridioides* *difficile* infection (CDI)
		- Chronic proton pump inhibitor use
		- Severe CDI
			* White blood cell (WBC) ≥15,000 cells/mm3 or serum creatinine >1.5 mg/dL
		- Ribotype 027/078/244 infections
	+ Prior CDI treatments
		- For example: Zinplava, Vancomycin, Fidaxomicin
	+ Previous hospitalizations
	+ Any potential contraindications
	+ Current symptoms
	+ Any relevant laboratory test results
		- Stool test for toxigenic CDI or polymerase chain reaction (PCR) test
	+ Consulting physician
		- Infectious disease specialist or gastroenterologist
* Treatment Guidelines1-3
	+ [Infectious Disease Society of America and Society of Healthcare Epidemiology of America (SHEA) Guidelines](https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/)
	+ [American College of Gastroenterology (ACG) Guidelines](https://journals.lww.com/ajg/fulltext/2021/06000/acg_clinical_guidelines__prevention%2C_diagnosis%2C.12.aspx)
* [Full Prescribing Information for VOWST](https://www.serestherapeutics.com/our-products/VOWST_PI.pdf)
* Scientific Publications4-8
	+ [Feuerstadt P, Louie TJ, Lashner B, et al. SER-109, an Oral Microbiome Therapy for Recurrent *Clostridioides difficile* Infection. *N Engl J Med*. 2022;386(3):220-229.](https://www.nejm.org/doi/10.1056/NEJMoa2106516)
	+ [Sims MD, Khanna S, Feuerstadt P, et al. Safety and tolerability of SER-109 as an investigational microbiome therapeutic in adults with recurrent *Clostridioides difficile* infection: a phase 3, open-label, single-arm trial. *JAMA Netw Open.* 2023;6(2):e225575](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2801350).
	+ Rosenberg J, Ritter T. Practical use of fecal microbiota spores, live-brpk (formerly SER-109): an oral therapeutic for the prevention of recurrent *Clostridioides difficile* infection. *Expert Rev Anti Infect Ther*. 2023;21(7):687-690.
	+ [Allegretti JR, Kearney S, Li N, et al. Recurrent Clostridium difficile infection associates with distinct bile acid and microbiome profiles. *Aliment Pharmacol Ther*. 2016;43(11):1142-1153.](https://onlinelibrary.wiley.com/doi/10.1111/apt.13616)
	+ [Garey KW, Jo J, Gonzales-Luna AJ, et al. Assessment of quality of life among patients with recurrent Clostridioides difficile infection treated with investigational oral microbiome therapeutic SER-109: secondary analysis of a randomized clinical trial. *JAMA Netw Open.* 2023;6(1):e2253570.](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800818)

**References:** **1.** 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. *Clin Infect Dis*. 2021;73(5):e1029-e1044. **2.** Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical guidelines: prevention, diagnosis, and treatment of *Clostridioides difficile* infections. *Am J Gastroenterol*. 2021;116(6):1124-1147. [published correction appears in Am J Gastroenterol. 2022 Feb 1;117(2):358.] **3.** VOWST Prescribing Information. Cambridge, MA: Seres Therapeutics, Inc. and Nestlé Health Science. **4.** Feuerstadt P, Louie TJ, Lashner B, et al. SER-109, an oral microbiome therapy for recurrent *Clostridioides difficile* infection. *N Engl J Med*. 2022;386(3):220-229. **5.** Sims MD, Khanna S, Feuerstadt P, et al. Safety and tolerability of SER-109 as an investigational microbiome therapeutic in adults with recurrent *Clostridioides difficile* infection: a phase 3, open-label, single-arm trial. *JAMA Netw Open.* 2023;6(2):e225575. **6.** Rosenberg J, Ritter T. Practical use of fecal microbiota spores, live-brpk (formerly SER-109): an oral therapeutic for the prevention of recurrent *Clostridioides difficile* infection. *Expert Rev Anti Infect Ther*. 2023;21(7):687-690. **7.** Allegretti JR, Kearney S, Li N, et al. Recurrent *Clostridium difficile* infection associates with distinct bile acid and microbiome profiles. *Aliment Pharmacol Ther*. 2016;43(11):1142-1153. **8.** Garey KW, Jo J, Gonzales-Luna AJ, et al. Assessment of quality of life among patients with recurrent *Clostridioides difficile* infection treated with investigational oral microbiome therapeutic SER-109: secondary analysis of a randomized clinical trial. *JAMA Netw Open.* 2023;6(1):e2253570.

VOW-PM-USA-0031 01/24

[Physician’s Letterhead]

[Date]

[Name of Pharmacy Director/Payer Contact]

[Contact Title]

[Name of Health Insurance Company]

[Address]

[City, State, ZIP Code]

Re: Coverage for VOWST

**Patient**: [Patient Name]

**Date of Birth**: [Date]

**Diagnosis**: [Diagnosis], [ICD-10-CM]

**Group/Policy Number**: [Number]

**Policyholder**: [Policyholder Name]

Dear [Pharmacy Director/Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity of VOWST**™** (fecal microbiota spores, live-brpk) capsules, 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)*.* Since VOWST must be administered within 2 to 4 days after completing treatment with standard-of-care antibacterials, I am requesting an expedited review so that [Patient Name] does not miss the VOWST treatment window.

The following is a summary of my patient's medical history and diagnosis. Please refer to the [List any Enclosures] enclosed with this letter.

**Summary of Patient’s Medical History and Diagnosis**

This case involves my [Patient Name], who is aged [Age] years and was initially diagnosed with rCDI [ICD-10-CM] on [Date]. [Patient Name] has been in my care since [Date].

[Provide a discussion of the patient’s clinical history, current symptoms, and severity of condition, past and/or history of CDI and rCDI, antibacterial treatments, previous hospitalizations, any potential contraindications, and any relevant laboratory test results, highlighting the factors leading you to recommend use of the product]. [Patient Name] is currently receiving [antibacterial regimen] and scheduled to begin VOWST therapy on [Date].

**Rationale for Treatment**

[Include your clinical rationale and reasons for prescribing the product]

Based on the information provided, I have determined that VOWST is medically necessary and reasonable to treat [Patient Name’s] rCDI. Please approve coverage of VOWST for [Patient Name’s] based on my clinical judgment.

Please refer to the enclosed supporting documents for further details, and do not hesitate to call me at [Phone Number] if you have any questions or if you require additional information. Thank you for your attention to this timely and urgent matter.

Sincerely,

[Prescribing Physician Name and Credentials]

[NPI Number]

Enclosures: [List any Enclosures, such as:

* Full Prescribing Information for VOWST
* Clinical Notes and Records
	+ ICD-10 code, diagnosis name, and dates
	+ Past treatments and/or failed treatments
	+ History of hospitalizations
	+ Scientific publication
	+ Treatment guidelines]