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

**SAMPLE LETTER OF APPEAL**

If coverage is denied, the treating physician may submit a request to appeal or reconsider the coverage denial. The following letter is for information purposes and only intended as a sample letter of appeal for VOWST to illustrate the types of information that should be considered for inclusion. Health plan requirements may vary, so the prescriber should refer to the explanation of benefits and prior authorization denial or coverage information specific to the patient’s health plan before completing a letter of appeal. The decision to prescribe VOWST as well as submit any letter of appeal 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 an expedited Appeal decision 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-0098 12/23

**[Physician’s Letterhead]**

**[Date]**

**[Name of Pharmacy Director/Payer Contact]**

**[Contact Title]**

**[Name of Health Insurance Company]**

**[Address]**

**[City, State, ZIP Code]**

RE: Appeal for Denial of VOWST

**Patient:** [Patient Name]

**Date of Birth:** [Date]

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

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

**Policyholder:** [Policyholder Name]

**Reference/Case Number:** [Number]

Dear [Pharmacy Director/Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to request that you reconsider your decision to deny coverage 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). Based on your letter of denial dated [date], VOWST has been denied because [reason(s) for denial]. Since VOWST must be administered within
2 to 4 days after completing treatment with standard-of-care antibacterials, I am requesting an expedited review for reconsideration of approval 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**

VOWST was approved by the FDA on [Date]. I continue to believe that VOWST is appropriate and medically necessary for [Patient Name] for the following reasons:

[Treatment plan; clinical rationale and reasons for prescribing VOWST].

[Include if patient has any risk factors mentioned below].

Based on my recommendation, I ask that you reconsider and approve coverage for VOWST to treat [Patient Name’s] rCDI.

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
* Copy of the FDA approval letter
* Clinical Notes and Records
	+ ICD-10 code, diagnosis name, and dates
	+ Letter of medical necessity
	+ Past treatments and/or failed treatments
	+ History of hospitalizations
	+ Scientific publication
	+ Treatment guidelines]