

# VOWST™

(fecal microbiota spores,  
live-brpk) capsules

## Prior Authorization (PA) and Appeals Resource for VOWST

This informational resource provides considerations for health plan requirements that may be helpful when submitting PAs or appeals when seeking VOWST coverage for your patients

### INDICATION

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).  
Limitation of Use: VOWST is not indicated for treatment of CDI.

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

**Transmissible infectious agents:** Because VOWST is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Report any infection that is suspected to have been transmitted by VOWST to Aimmune Therapeutics, Inc. at 1-833-246-2566.

**Potential presence of food allergens:** VOWST may contain food allergens. The potential to cause adverse reactions due to food allergens is unknown.

This resource is provided for informational purposes only and does not constitute reimbursement or legal advice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine medical necessity and submit appropriate codes and information to third-party payors. This document includes possible codes that may be used, but it is the provider's sole responsibility to determine and submit appropriate codes to describe the patient's condition. Nestlé and Seres Therapeutics cannot guarantee coverage. Nestlé and Seres Therapeutics do not promote the use of their products outside the FDA-approved labeling.

# Considerations for Completing a PA for Patients with Recurrent *C. difficile* to be Treated with VOWST

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A benefits investigation (BI) may indicate that a PA is required prior to the health plan approving coverage for VOWST. PA criteria and forms may vary by health plan, but below are considerations when completing a PA submission:

## STEP

### 1 Complete the proper PA form for the patient's health plan

#### Remember to:

- **Provide patient and insurance information**
- **Include prescriber information**
  - Name, practice, NPI/DEA number
- **Diagnosis and coding**
  - Potential ICD-10 diagnosis code(s)
  - Number of recurrences
- **Potential ICD-10 diagnosis codes for rCDI**
  - **A04.71** – Enterocolitis due to *Clostridium difficile*, recurrent<sup>1</sup>
  - **A04.72** – Enterocolitis due to *Clostridium difficile*, not specified as recurrent<sup>2</sup>
- **Dosing information**
  - Complete antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with VOWST
  - Drink 296 mL (10 oz) magnesium citrate, on the day before and at least 8 hours prior to taking the **first** dose of VOWST. Do not eat or drink, except for small amount of water, for at least 8 hours prior to taking the first dose
  - The dosage of VOWST is 4 capsules taken orally once daily for 3 consecutive days. Take each dose (4 capsules) on an empty stomach prior to the first meal of the day
- **Include previously tried/failed therapies**
  - Include when therapies took place
- **Include relevant labs/testing**
  - Include dates of labs/testing
- **Consultation with specialists**
  - Include dates of consultations

## STEP

### 2 Provide supplemental documentation as needed

#### These documents may include:

- Patient clinical notes
  - Lab results
  - Chart notes
  - History of *C. difficile* and recurrences
  - History of hospitalizations
  - Risk factors for *C. difficile* recurrence
- A copy of the full Prescribing Information for VOWST
- If applicable, clinical studies or peer-reviewed journal articles documenting the medical effectiveness of VOWST

**Most PA forms have the option for an expedited or urgent review. If the health plan has this option, consider noting on the form before submitting.**

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## STEP 3

### If needed, include a letter of medical necessity

#### It is important to:

- Keep it concise
- Include patient and prescription information
- Provide a summary of your patient's medical history and diagnosis
- State your treatment rationale
- Include your name, signature and date
- Refer to [vowsthcp.com](http://vowsthcp.com) for VOWST Sample Letter Medical Necessity

## STEP 4

### Submit and monitor the PA request

#### Determine whether the health plan prefers the PA be submitted via:

- Phone
- Fax
- Email
- Online (health plan or a third-party website)
- Submission information is often listed on the PA form or health plan website. Include all supplemental documents in your submission

**For additional information, contact your Nestlé Health Science Field Sales Representative, or call the VOWST Voyage Support Program at 1-888-356-5444.**

If needed for any questions regarding the patient's VOWST prescription, the following specialty pharmacies may be reached for assistance.

Specialty Pharmacy	Phone	Fax	Hours
Amber	1-844-703-3647	1-833-253-8775	M-F: 8 AM-8 PM ET Sat: 8 AM-6 PM ET Pharmacist: 24/7
Orsini	1-800-485-4885	1-877-640-5179	M-F: 9 AM-7 PM ET Pharmacist: 24/7

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# How to Handle a Denied PA and Steps for Appealing

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You can appeal a denial by contacting the health plan directly and/or request a peer-to-peer discussion regarding the patient, the clinical issues, and the reasons for requesting VOWST. You may also submit an appeal to the health plan.

## STEP 1

### Understand the reason for denial

There could be several reasons that a PA may be denied:

Reason for denial	Considerations for avoiding denial
Incomplete or incorrect information	Review and confirm PA information, fill in any missing information and resubmit. Ensure correct dosing and ICD-10 code is captured.
Did not try & fail formulary alternative	Include information on why VOWST is necessary and how you expect it to help the patient.
Medication not covered	You can ask insurance plans for a medical exception, if applicable, or to reevaluate or submit a Letter of Appeal.

You may also call and speak with the health plan to help you better understand the reason for the denial and determine how to quickly resolve the matter.

## STEP 2

### Complete the proper appeal form for the patient's health plan

**Remember:**

- Appeal forms can be obtained through the health plan's website or by contacting the health plan's customer service
- Make sure to follow important guidelines and timeframes

## STEP 3

### If needed, include a formal letter of appeal

**It is important to:**

- Keep it concise
- Include patient and prescription information
- Provide a summary of your patient's medical history and diagnosis
- State your treatment rationale
- Include your name, signature and date
- Refer to [vowsthcp.com](http://vowsthcp.com) for VOWST Sample Letter of Appeal

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# How to Handle a Denied PA and Steps for Appealing (continued)

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## STEP 4

### Provide supporting documentation, if needed

#### This may include:

- Patient clinical notes and relevant medical records
- Treatment history
- Clinical studies or peer-reviewed journal articles documenting the medical effectiveness of VOWST
- VOWST full Prescribing Information

## STEP 5

### Submit and monitor the appeal

#### Determine whether the information should be submitted via:

- Phone
- Fax
- Email
- Online (health plan or third-party website)

This information is often listed in the denial.

There are often multiple levels of appeal depending on the health plan. Please be sure to connect with the health plan directly to discuss all options for appeal.

#### If the appeal is denied:

- Your patient can ask for an external review (by an independent, accredited medical professional) or a peer review
- If all attempts at coverage are denied by the primary health plan, and your patient has a secondary health plan, you may seek coverage through a secondary health plan, if applicable

# How the VOWST Voyage™ Support Program may help your patients

The VOWST Voyage Support Program helps your patients navigate coverage and benefits assistance as well as access support. Visit [vowsthcp.com](http://vowsthcp.com) to enroll your patients in the VOWST Voyage Support Program and find helpful resources.

## Getting Started:

1. Download the enrollment form on [vowsthcp.com](http://vowsthcp.com)
2. Complete the form, and ensure your patient signs the patient authorization
3. Fax the completed form to VOWST Voyage Support Program (1-888-234-6987)

## Coverage and Benefits Assistance

We assist your patients with:

- Navigating insurance coverage and benefits
- Investigating other options for coverage and manufacturer-sponsored financial assistance programs that may help cover some of the out-of-pocket costs of VOWST for eligible patients



Phone: 1-888-356-5444  
Fax: 1-888-234-6987

Once VOWST Voyage Support Program receives the enrollment form, your patient will be contacted by a case manager to discuss insurance coverage and benefits, financial assistance options, and provide educational resources.

**For additional information, contact your Nestlé Health Science Field Sales Representative, or call the VOWST Voyage Support Program at 1-888-356-5444.**

## IMPORTANT SAFETY INFORMATION *(continued)*

### ADVERSE REACTIONS

The most common adverse reactions (reported in  $\geq 5\%$  of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).

### DRUG INTERACTIONS

Do not administer antibacterials concurrently with VOWST.

Please see full [Prescribing Information](#) and [Patient Information](#).

### References:

1. ICD-10 code lookup. Centers for Medicare and Medicaid Services website. <https://www.icd10data.com/ICD10CM/Codes/A00-B99/A00-A09/A04-/A04.71>. Accessed January 30, 2023.
2. ICD-10 code lookup. Centers for Medicare and Medicaid Services website. <https://www.icd10data.com/ICD10CM/Codes/A00-B99/A00-A09/A04-/A04.72>. Accessed January 30, 2023.

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