

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 Health Science cannot guarantee coverage. Nestlé Health Science does not promote the use of its products outside the FDA-approved labeling.

Considerations for Completing a PA for Patients with Recurrent CDI to be Treated with VOWST

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

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*, recurrent¹
 - **A04.72** – Enterocolitis due to *Clostridium difficile*, not specified as recurrent²
- **Dosing information**
 - Complete antibiotic 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.**

Considerations for Completing a PA for Patients with Recurrent CDI to be Treated with VOWST (continued)



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
- [Click here](#) for VOWST Sample Letter of 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	Monday to Friday: 8am-8pm ET Saturday: 8am-6pm ET
Orsini	1-800-485-4885	1-877-640-5179	Monday to Friday: 9am-7pm ET

How to Handle a Denied PA and Steps for Appealing

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 for VOWST Sample Letter of Appeal

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

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

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
- Treatment guideline

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 www.vowsthcp.com to enroll your patients in the VOWST Voyage Support Program and find helpful resources.

Enrollment in VOWST Voyage

Complete and submit the digital VOWST Enrollment Form and Prescription at www.vowsthcp.com

You can also download and fax the completed form to **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 financial assistance eligibility, and will be provided 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 Vowst-treated participants, and at a rate greater than placebo) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Aimmune Therapeutics at 1-833-AIM-2KNO (1-833-246-2566), or the FDA at 1-800-FDA-1088, or visit 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 October 10, 2024. 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 October 10, 2024.

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 Health Science cannot guarantee coverage. Nestlé Health Science does not promote the use of its products outside the FDA-approved labeling.



All trademarks are owned by Société des Produits Nestlé S.A., Vevey, Switzerland or used with permission.

© 2024 Nestlé. VOW-PM-USA-0082 11/24