Louisiana Medicaid
Fecal microbiota spores, live-brpk (Vowst™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for fecal microbiota spores, live-brpk (Vowst™)

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a confirmed diagnosis of least 2 recurrent episodes of Clostridioides difficile infection (rCDI) within 12 months (total of ≥ 3 episodes of CDI); **AND**
- The recipient has a positive stool test for C. difficile within the 30 days preceding the prior authorization request; **AND**
- The current episode of CDI must be controlled following standard-of-care antibacterial treatment, defined as < 3 unformed stools in 24 hours for 2 or more consecutive days; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of approval: 3 days

Reference

Vowst (fecal microbiota spores, live-brpk) [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc; April 2023. https://www.serestherapeutics.com/our-products/VOWST_PI.pdf

Revision / Date	Implementation Date
Policy created / May 2023	October 2023