# Vowst Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

| **Effective Date** | **Date of Origin** |
|---|---|
| 09-15-2025 | 08-17-2023 |

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|---|---|---|---|---|---|---|
| | | | | | | |
| Vowst | fecal microbiota spores, live-brpk caps | | M ; N ; O ; Y | N | | |

## POLICY AGENT SUMMARY QUANTITY LIMIT

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Day Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| Vowst | fecal microbiota spores, live-brpk caps | | 12 | Capsules | 12 | MONTHS | | | |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Vowst | fecal microbiota spores, live-brpk caps | | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Annual 2026 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL non-HMO Performance Full ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods |


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## CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Vowst | fecal microbiota spores, live-brpk caps | | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Annual 2026 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL non-HMO Performance Full ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The requested agent will be used to prevent the recurrence of Clostridioides difficile infection (CDI) **AND**<br>2. The patient has a diagnosis of recurrent CDI as defined by ALL of the following:<br>A. Greater than or equal to 3 episodes of CDI in a 12-month period **AND**<br>B. A positive C. difficile stool sample **AND**<br>C. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days **AND**<br>3. The patient has completed a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) for recurrent CDI at least 2 to 4 days before initiating treatment with the requested agent **AND**<br>4. The patient has had an adequate clinical response to a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days **AND**<br>5. The patient will NOT be using the requested agent in combination with any antibiotic regimen for any indication **AND**<br>6. If the patient has an FDA approved indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. There is support for using the requested agent for the patient's age for the requested indication **AND**<br>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>8. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Length of Approval:** One course per 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**The requested agent will also be approved when ONE of the following is met:**<br><br>1. The request is for a BCBS MT Fully Insured or MT HIM member **AND** |


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| Module | Clinical Criteria for Approval |
|---|---|
| | A. The patient is under the age of 18 years old **AND**<br>B. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] **AND**<br>D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] **OR**<br>2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:<br>A. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>B. The requested indication is a rare disease **AND**<br>C. ONE of the following:<br>1. The patient has another FDA labeled indication for the requested agent and route of administration **OR**<br>2. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**<br>3. ALL of the following:<br>A. The member resides in Ohio **AND**<br>B. The plan is Fully Insured or HIM Shop (SG) **AND**<br>C. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>D. ONE of the following:<br>1. The patient has another FDA labeled indication for the requested agent and route of administration **OR**<br>2. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**<br>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required<br><br>**Non-oncology compendia allowed:** DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)<br><br>**Oncology compendia allowed:** NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature<br><br>**Length of Approval:** One course per 12 months<br><br>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when the following is met: |


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| Module | Clinical Criteria for Approval |
|---|---|
| | 1. The requested quantity (dose) does NOT exceed the program quantity limit<br><br>**Length of Approval:** One course every 12 months |


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