

Firvanq[®] (vancomycin for oral solution)

Policy # 00945

Original Effective Date: 01/01/2026

Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Firvanq[®] (vancomycin oral solution) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Firvanq (vancomycin oral solution) will be considered when the following criteria are met:

- Patient has a diagnosis of *Clostridium difficile*-associated diarrhea OR enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains); AND
- Patient has tried and failed (e.g., intolerance or inadequate response) generic vancomycin capsules OR vancomycin oral solution unless there is clinical evidence or patient history that suggests these generic alternatives will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Firvanq (vancomycin oral solution) when the patient has not tried and failed one of the listed generic alternatives to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Firvanq (vancomycin oral solution) when the patient selection criteria are NOT met (with the exception of those denoted above as not medically necessary**) to be **investigational.***

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Background/Overview

Firvanq is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of *Clostridium difficile*-associated diarrhea and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Firvanq was approved by the Food and Drug Administration (FDA) via the 505(b)(2) pathway relying on safety and efficacy information from oral vancomycin 125 mg to support approval. Firvanq is supplied as a kit requiring reconstitution and is available in concentrations of 25 mg/mL or 50 mg/mL. Each kit includes a bottle of vancomycin powder for oral solution, available in strengths equivalent to 3.75 grams, 7.5 grams, or 15 grams of vancomycin, and a pre-measured grape-flavored diluent in a second bottle. The healthcare provider (i.e., pharmacist) must reconstitute the powder and diluent, resulting in a final volume of either 150 mL or 300 mL, depending on the kit selected.

Various dosage forms and strengths of vancomycin are commercially available. Both concentrations of Firvanq are available as generics, in addition to vancomycin 125 mg and 250 mg capsules and vancomycin oral solution 250 mg/5mL.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Firvanq is indicated in adults and pediatric patients less than 18 years of age for the treatment of *Clostridium difficile*-associated diarrhea and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

This policy is in place to ensure that Firvanq is used for an FDA approved indication. This policy is also intended to ensure that efficacious and economically sensible alternatives are utilized prior to the brand product. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using brand name Firvanq over the alternative generic vancomycin products.

References

1. Firvanq [package insert]. Azurity Pharmaceuticals. Wilmington, Massachusetts. Updated December 2021.

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Policy History

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11/06/2025 Medical Policy Committee review

11/12/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 11/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.