CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 513-E |

# Initial Step Therapy With Quantity Limit; Post Step Therapy Prior Authorization With Quantity Limit Vancomycin Oral Products

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Firvanq | vancomycin | All |
| Vancocin | vancomycin | capsules |

## Indications

### FDA-approved Indications

#### Vancocin

Vancocin is indicated for the treatment of Clostridioides difficile-associated diarrhea. Vancocin is also used for the treatment of enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) in adult and pediatric patients less than 18 years of age.

##### Limitations of Use

* Parenteral administration of vancomycin is not effective for the above infections; therefore, Vancocin must be given orally for these infections.
* Orally administered Vancocin is not effective for other types of infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancocin and other antibacterial drugs, Vancocin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

#### Firvanq

Firvanq is indicated for the treatment of Clostridium difficile-associated diarrhea in adults and pediatric patients less than 18 years of age.

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

##### Important Limitations of Use

* Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.
* Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Firvanq and other antibacterial drugs, Firvanq should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

## Screen Out Logic with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 10 day supply of oral metronidazole OR at least a 7 day supply of Vancocin (vancomycin hydrochloride capsules) OR at least a 7 day supply of Firvanq (vancomycin hydrochloride powder for oral solution) OR a 10 day supply of Dificid (fidaxomicin) within the past 60 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the screen out logic criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the screen out logic criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

## Initial Limit Quantity

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

These drugs are for short-term acute use.

| Drug | Limit |
| --- | --- |
| Firvanq (vancomycin) powder for oral solution (all strengths) | 450 mL / fill |
| Vancocin (vancomycin) capsules (all strengths) | 80 capsules / fill |

## Coverage Criteria

### Enterocolitis

Authorization may be granted when the patient has a diagnosis of enterocolitis caused by Staphylococcus aureus.

### C.difficile-Associated Diarrhea

Authorization may be granted when the patient has a diagnosis of C.difficile-associated diarrhea.

## Quantity Limits Apply

### Post Limit Quantity

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

These drugs are for short-term acute use.

| Drug | Limit |
| --- | --- |
| Firvanq (vancomycin) powder for oral solution (all strengths) | 450 mL / fill |
| Vancocin (vancomycin) capsules (all strengths) | 80 capsules / fill |

## Duration of Approval (DOA)

* 513-E: DOA: 14 days.

## References

1. Firvanq [package insert]. Wilmington, MA: Azurity Pharmaceuticals; February 2022.
2. Vancocin [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; December 2021.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 4, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/04/2024).
5. McDonald L, Gerding D, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infectious Diseases 2018:66 (7): e1-e48. https://doi.org/10.1093/cid/cix1085. Accessed November 4, 2024.
6. Johnson S, Lavergne V, Skinner A et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases 2021;73 (5): e1029–e1044. https://doi.org/10.1093/cid/ciab549 . Accessed November 4, 2024.
7. Kelly CR, Fischer M, Allegretti JR, LaPlante K, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. Am J Gastroenterol. 2021 Jun 1;116(6):1124-1147.