Clinical Policy: Vancomycin Oral (Firvanq, Vancocin)

Reference Number: CP.CPA.166
Effective Date: 11.16.16
Last Review Date: 11.23
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Vancomycin oral (Firvanq®, Vancocin®) is a glycopeptide antibiotic.

FDA Approved Indication(s)

Firvanq and Vancocin are indicated in adults and pediatric patients less than 18 years of age for the treatment of:

- *Clostridium difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Limitation(s) of use:

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Firvanq and Vancocin are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. *Clostridium difficile*-Associated Diarrhea (must meet all)**:**

1. Diagnosis of *Clostridium difficile*-associated diarrhea;
2. If request is for brand Vancocin, member must use generic vancomycin capsules*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin capsules*
3. If request is for Firvanq, member must use generic vancomycin oral solution*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin oral solution*
4. Dose does not exceed 2 g per day.

Approval duration: Up to 14 days

B. Staphylococcal Enterocolitis (must meet all)**:**

1. Diagnosis of staphylococcal enterocolitis;

2. If request is for brand Vancocin, member must use generic vancomycin capsules*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin capsules*
3. If request is for Firvanq, member must use generic vancomycin oral solution*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin oral solution*
4. Dose does not exceed 2 g per day.

Approval duration: Up to 10 days

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. If request is for brand Vancocin, member must use generic vancomycin capsules*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin capsules*
3. If request is for Firvanq, member must use generic vancomycin oral solution*, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for generic vancomycin oral solution*
4. If request is for a dose increase, new dose does not exceed 2 g per day.

Approval duration: Up to 12 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents;

B. Systemic infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information
- Oral vancomycin is not absorbed systemically and is not effective for other types of infection.
- Per 2017 IDSA guidelines for C. difficile-associated diarrhea, vancomycin and fidaxomicin are preferred first-line treatments for non-severe, recurrent, and severe disease in adults. Metronidazole is recommended as an alternative agent, if vancomycin and fidaxomicin are unavailable.
- Per 2021 IDSA guidelines for C. difficile infection (CDI), fidaxomicin rather than a standard course of vancomycin is recommended for initial CDI episode, although vancomycin remains an acceptable alternative. In patients with recurrent CDI episodes, fidaxomicin (standard or extended pulsed regimen) rather than a standard course of vancomycin is recommended. Vancomycin in a tapered and pulsed regimen or vancomycin as a standard course are acceptable alternatives for a first CDI recurrence. For patients with multiple recurrences, vancomycin in a tapered and pulsed regimen, vancomycin followed by rifaximin, and fecal microbiota transplantation are options in addition to fidaxomicin.

- FDA labeling and guidelines recommend duration of therapy to be 10 days. However, the guidelines recommend considering extending treatment to up to 14 days for patients with delayed response to treatment.
- For recurrence, a second course of vancomycin for 10 to 14 days is a dosing regimen option per guidelines.
- For recurrence, tapered and pulsed regimens of vancomycin are alternative dosing regimens to the standard vancomycin regimen per guidelines. Examples of the regimen include:
  - For adults: vancomycin PO 125 mg QID for 10 to 14 days, then BID for 1 week, then QD for 1 week, then every 2 or 3 days for 2 to 8 weeks.
  - For pediatrics: vancomycin PO 10 mg/kg (max 125 mg QID) for 10 to 14 days, then 10 mg/kg (max 125 mg BID) for 1 week, then 10 mg/kg (max 125 mg QD) for 1 week, then 10 mg/kg (max 125 mg every 2 or 3 days) for 2 to 8 weeks.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
C. difficile-associated diarrhea	Adult (≥ 18 years): 125 mg PO QID Pediatric (< 18 years): 40 mg/kg PO in 3 or 4 divided doses	2 g/day
Staphylococcal enterocolitis	Adult (≥ 18 years): 500 mg to 2 g PO in 3 or 4 divided doses/day Pediatric (< 18 years): 40 mg/kg PO in 3 or 4 divided doses	2 g/day

VI. Product Availability

Drug Name	Availability
Vancomycin (Vancocin)	Oral capsules: 125 mg, 250 mg
Vancomycin (Firvanq)	Powder for oral solution: 3.75 g, 7.5 g, 15.0 g

VII. References

1. Vancocin Prescribing Information. Baudette, MN: ANI Pharmaceuticals, Inc.; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a078d9c2-f89c-4f9f-8ded-60ffb2983c3f. Accessed June 27, 2023.
2. Firvanq Prescribing Information. Wilmington, MA: Azurity Pharmaceuticals; January 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208910s007lbl.pdf. Accessed June 27, 2023.
3. Pelaez T, Alcala L, Rodriguez-Creixems M, et al. Reassessment of Clostridium difficile susceptibility to metronidazole and vancomycin. Antimicob Agents Chemother. 2002;46:1647-1650.
4. Joyce AM, Burns, DL. Recurrent Clostridium difficile colitis: Tackling a tenacious nosocomial infection. Postgradmed. 2002:112(5):53-54, 57-58, 65.
5. Musher DM, Logan N, Hamill RJ et al. Nitazoxanide for the treatment of Clostridium difficile colitis. Clin Infec Dis. 2006;43(4):421-427.

6. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 updated by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. March 2018;66(7):987-994.
7. 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: 24 June 2021. Available at: https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/. Accessed June 27, 2023.
8. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections, The American Journal of Gastroenterology. June 2021; 116 (6): 1124-1147.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.08.19	11.19
4Q 2020 annual review: added Firvanq to the policy; references reviewed and updated.	08.04.20	11.20
4Q 2021 annual review: no significant changes; retire WCG.CP.CPA.166; references reviewed and updated.	07.20.21	11.21
4Q 2022 annual review: added requirement for use of generic formulation; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.18.22	11.22
4Q 2023 annual review: no significant changes; added "prior authorization may be required for generic vancomycin" asterisks in initial and continued therapy criteria; references reviewed and updated.	06.27.23	11.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.