

Clinical Pharmacy Program Guidelines for Vancomycin

Program	Prior Authorization
Medication	Firvanq (vancomycin) oral solution, Vancocin (vancomycin) capsules, vancomycin oral solution
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Vancocin (vancomycin) capsules and oral solution and Firvanq (vancomycin) oral solution are indicated for the treatment of *Clostridioides difficile*- associated diarrhea (previously known as *Clostridium difficile*- associated diarrhea) and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.

2. Coverage Criteria:

<p>A. <u><i>Clostridioides difficile</i>-associated diarrhea (CDAD) [previously known as <i>Clostridium difficile</i>- associated diarrhea]</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Vancomycin capsules, vancomycin oral solution, or Firvanq oral solution will be approved based on <u>both</u> of the following:</p> <p>(1) Diagnosis of <i>Clostridioides difficile</i>-associated diarrhea (CDAD) [previously known as <i>Clostridium difficile</i>- associated diarrhea]</p> <p style="text-align: center;">-AND-</p> <p>(2) If the request is for Vancocin (vancomycin capsules) or vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq.</p> <p>NOTE: Vancocin (vancomycin capsules) and generic vancomycin oral solution are non-preferred. Firvanq is preferred.</p>

Authorization will be issued for 10 days.

2. Reauthorization

a. Vancomycin capsules, vancomycin oral solution, or Firvanq oral solution will be approved based on **both** the following:

(1) Recurrence of *Clostridioides* [previously known as *Clostridium*] *difficile* infection after prior treatment with oral vancomycin

-AND-

(2) If the request is for Vancocin (vancomycin capsules) or vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq.

NOTE: Vancocin (vancomycin capsules) and generic vancomycin oral solution are non-preferred. Firvanq is preferred.

Authorization will be issued for 12 weeks.

B. Staphylococcal enterocolitis

1. Vancomycin capsules or Firvanq oral solution will be approved based on **both** of the following:

(1) Diagnosis of enterocolitis due to *Staphylococcus aureus*

-AND-

(2) If the request is for vancomycin capsules or vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq.

NOTE: Vancocin (vancomycin capsules) and generic vancomycin oral solution are non-preferred. Firvanq is preferred.

Authorization will be issued for 10 days.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Vancocin [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; 2018.
2. McDonald, 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), Clin Infect Dis. 2018 April 19;66(7):e1-48.
3. Firvanq [package insert]. Wilmington, MA: CutisPharma, Inc.; 2018.
4. Kelly C. Clostridioides (formerly Clostridium) difficile infection in adults: Treatment and prevention. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 18, 2020.)
5. Vancomycin Hydrochloride for Oral Solution [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; 2019.

Program	Prior Authorization –Vancomycin
Change Control	
Date	Change
June 2009	Criteria taken from previously approved AmeriChoice policy. Policy reformatted.
Dec 2010	Annual Review
March 2011	Annual Review
March 2012	Annual Review
September 2013	Created reauthorization criteria for CDAD. Created criteria specifically for Staphylococcal enterocolitis
September 2014	Criteria reviewed due to FDA approval of First-Vancomycin oral solution compounding kit. First-Vancomycin oral solution compounding kit is non-preferred. No change to clinical criteria.
December 2015	Annual Review
November 2016	Annual review, updated policy template
August 2017	Changed authorization duration for enterocolitis due to <i>Staphylococcus aureus</i> per treatment guidelines

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October 2018	Added Firvanq. Removed step through metronidazole for CDAD based on updated IDSA treatment guidelines. Updated CDAD authorization durations. Updated references.
April 2019	Annual Review. Updated background and references.
September 2019	Updated CDAD reauthorization language to include a step through Firvanq for vancomycin capsule requests.
April 2020	Added vancomycin oral solution. Renamed <i>Clostridium difficile</i> to <i>Clostridioides difficile</i> .