



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Infectious Disease – Vancomycin (Oral) Drug Quantity Management Policy – Per Rx
- Firvanq® (vancomycin hydrochloride oral solution – Azurity)
 - Vancocin® (vancomycin capsules – ANI, generic)
 - Vancomycin oral solution (generic only)

REVIEW DATE: 12/14/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Vancomycin (oral), an antimicrobial, is indicated for the following uses:¹⁻³

- ***Clostridioides difficile***- (formerly known as *Clostridium difficile*) associated diarrhea.
- **Enterocolitis** caused by ***Staphylococcus aureus*** (including methicillin-resistant strains).

Dosing

Adult Dosing

For the treatment of *C. difficile*-associated diarrhea in adults, the recommended dose of oral vancomycin is 125 mg four times daily for 10 days.¹⁻³ For the treatment of staphylococcal enterocolitis in adults, a total daily dose of 500 mg to 2 grams orally in three or four divided doses for up to 10 days is recommended.¹⁻³

Pediatric Dosing

In pediatric patients (< 18 years of age), the recommended dose of oral vancomycin is 40 mg/kg in three or four divided doses for up to 10 days (for either indication).¹⁻³ The total daily dose should not exceed 2 grams.

Availability

Availability of the oral vancomycin products is in the Drug Quantity Limit table below.

Guidelines

The Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Practice Guidelines for *C. difficile* Infection (2017 for adults and children; 2021 focused update for adults) note that a tapered and pulsed regimen of oral vancomycin is a treatment option for adult and pediatric patients who experience recurrent *C. difficile* infections.^{4,5} An example of a tapered/pulsed vancomycin regimen is: 125 mg 4 times a day for 10 to 14 days, 2 times a day for 7 days, once daily for 7 days, and then once daily every 2 to 3 days for 2 to 8 weeks.

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage therapy duration and provide for dose consolidation of oral vancomycin. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits*

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Vancomycin capsules (Vancocin®, generic)	125 mg capsules	40 capsules	40 capsules
	250 mg capsules	80 capsules	80 capsules
Firvanq® (vancomycin hydrochloride oral solution, generic to 50 mg/mL only)	25 mg/mL oral solution [†]	300 mL	300 mL
	50 mg/mL oral solution [†]	450 mL	450 mL
Vancomycin oral solution (generic only)	250 mg/5 mL (50 mg/mL) oral solution [‡]	450 mL	450 mL

* Quantity limits for the oral vancomycin products provide enough drug for a 10-day supply at four times daily dosing; [†] Each bottle contains either 150 mL or 300 mL oral solution following reconstitution; [‡] Each bottle contains either 80 mL, 150 mL, or 300 mL of oral solution following reconstitution.

Infectious Disease – Vancomycin (Oral) Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Firvanq 25 mg/ml oral solution

1. If the patient requires treatment for a recurrence of *C. difficile* infection, approve a one-time override for the requested quantity not to exceed 600 mL at retail or home delivery.

Note: A quantity of 600 mL provides a quantity sufficient for a vancomycin dose of 125 mg four times daily x 14 days, followed by 125 mg twice daily x 7 days, 125 mg daily x 7 days and then 125 mg once every 2 to 3 days for 2 to 8 weeks.

Firvanq 50 mg/ml oral solution

No overrides recommended.

Vancomycin 125 mg capsules (Vancocin, generic)

1. If the patient requires treatment for a recurrence of *C. difficile* infection, approve a one-time override for the requested quantity not to exceed 105 capsules at retail or home delivery.

Note: A quantity of 105 capsules provides a quantity sufficient for a vancomycin dose of 125 mg four times daily x 14 days, followed by 125 mg twice daily x 7 days, 125 mg daily x 7 days and then 125 mg once every 2 to 3 days for 2 to 8 weeks.

Vancomycin 250 mg capsules (Vancocin, generic)

No overrides recommended.

Vancomycin 250 mg/5 ml oral solution

No overrides recommended.

REFERENCES

1. Vancocin® capsules [prescribing information]. Baudette, MN: ANI; December 2021.
2. Firvanq® oral solution [prescribing information]. Wilmington MA: Azurity; January 2021.
3. Vancomycin hydrochloride powder for solution [prescribing information]. Baudette MN: ANI; March 2021.
4. McDonald LC, Gerding DN, 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). *Clin Infect Dis*. 2018;66(7):e1–e48.
5. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guidelines 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. *Clin Infect Dis*. 2021;73(5):e1029–e1044.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>Vancomycin 125 mg capsules (Vancocin, generic): Home delivery quantity limit changed from 120 capsules to 40 capsules per Rx. No change to retail quantity limit.</p> <p>Vancomycin 250 mg capsules (Vancocin, generic): Home delivery quantity limit changed from 240 capsules to 80 capsules per Rx. No change to retail quantity limit.</p> <p>Firvanq 25 mg/mL oral solution: Home delivery quantity limit changed from 900 mL to 300 mL. No change to retail quantity limit.</p> <p>Firvanq 50 mg/mL oral solution: Home delivery quantity limit changed from 1,350 mL to 450 mL. No change to retail quantity limit.</p> <p>Vancomycin 50 mg/mL oral solution: Home delivery quantity limit changed from 1,350 mL to 450 mL. No change to retail quantity limit.</p>	12/07/2022
Annual Revision	No criteria changes.	12/14/2023

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