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Drug Quantity Management – Per Rx Infectious Disease – Vancomycin (Oral)

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Product Identifier(s)

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National Formulary Medical Necessity

Drugs Affected

- Firvanq® (vancomycin hydrochloride oral solution)
- Vancocin® (vancomycin capsules – generic)
- Vancomycin oral solution (generic only)

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®	25 mg/mL oral solution†	300 mL	300 mL

(vancomycin hydrochloride oral solution)	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 oral solution following reconstitution.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Firvanq 25 mg/ml oral solution

1. If the individual 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 individual 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.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Vancomycin (oral), an antimicrobial, are 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.

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.

Revision History

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

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