Original Effective Date: 06/01/2013
Current Effective Date: 03/28/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C5325-C

Vancocin (vancomycin) Capsules

PRODUCTS AFFECTED

Vancocin (vancomycin) Capsules, vancomycin caps

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Clostridioides difficile-associated diarrhea, Enterocolitis caused by Staphylococcus aureus (including methicillin- resistant strains)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:
1. Documentation member has an infection caused by or strongly suspected to be caused by a type

of pathogen and site of infection within the FDA label

AND

2. The member has experienced inadequate treatment response to PREFERRED formulary product (Vancomycin oral solution [Firvanq])
   NOTE: For recurrent infection please see chart in Appendix. There is no literature that supports any brand product over another.

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: Up to 10 days, For C. difficile associate diarrhea disease recurrence treatment up to 12 weeks, Continuation of therapy: N/A

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
None

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Glycopeptides

FDA-APPROVED USES:
Indicated in adult and pediatric patients (less than 18 years of age) for the treatment of Clostridioides difficile-associated diarrhea and enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains).
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 bacteria.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Recommendations for the Treatment of Clostridioides difficile Infection in Adults (IDSA, 2021)

Clinical Presentation	Recommended and Alternative Treatments
Initial CDI Episode	Preferred: Fidaxomicin 200 mg given twice daily for 10 days
	Alternative: Vancomycin 125 mg given 4 times daily by mouth for 10 days
	Alternative for nonsevere CDI, if above agents are unavailable: Metronidazole, 500 mg 3 times daily by mouth for 10–14 days
First CDI recurrence	Preferred: Fidaxomicin 200 mg given twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days
	Alternative: Vancomycin by mouth in a tapered and pulsed regimen
	Alternative: Vancomycin 125 mg given 4 times daily by mouth for 10 days
	Adjunctive treatment: Bezlotoxumab 10 mg/kg given intravenously once during administration of SOC antibiotics
Second or subsequent CDI recurrence	Fidaxomicin 200 mg given twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days
	Vancomycin by mouth in a tapered and pulsed regimen
	Vancomycin 125 mg 4 times daily by mouth for 10 days followed by rifaximin 400 mg 3 times daily for 20 days
	Fecal microbiota transplantation
	Adjunctive treatment: Bezlotoxumab 10 mg/kg given intravenously once during administration of SOC antibiotics
Fulminant CDI	Vancomycin 500 mg 4 times daily by mouth or by nasogastric tube. If ileus, consider adding rectal instillation of vancomycin. Intravenously administered metronidazole (500 mg every 8 hours) should be administered together with oral or rectal vancomycin, particularly if ileus is present

BACKGROUND AND OTHER CONSIDERATIONS

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vancocin (vancomycin) Capsules are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Vancocin (vancomycin) Capsules include: known hypersensitivity to vancomycin.

OTHER SPECIAL CONSIDERATIONS:
Parenteral administration of vancomycin is not effective for Clostridioides difficile-associated diarrhea or enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains). Orally administered Vancocin capsules are not effective for other types of infections.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical*

Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vancocin CAPS 125MG
Vancocin CAPS 250MG
Vancomycin HCl CAPS 125MG
Vancomycin HCl CAPS 250MG

REFERENCES

1. Vancocin (vancomycin hydrochloride) [prescribing information]. Baudette, MN: ANI Pharmaceuticals; December 2021.
2. Firvanq (vancomycin hydrochloride) [prescribing information]. Wilmington, MA: Azurity Pharmaceuticals; December 2021.
3. Johnson S, Lavergne V, Skinner AM, 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. Clin Infect Dis. 2021;73(5):e1029-e1044. doi:10.1093/cid/ciab549

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q1 2025
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Appendix References	Q1 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Duration of Approval Quantity Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file