Original Effective Date: 08/01/2018
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C14575-A

Vibativ (telavancin)

PRODUCTS AFFECTED

Vibativ (telavancin)

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:
Complicated skin and skin structure infections (cSSSI), Hospital-acquired and ventilator- associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of Staphylococcus aureus, Staphylococcus aureus (MRSA) bacteremia

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. FOR 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 or compendia supported.
   AND
2. (a) Documentation of FDA labeled contraindication to Vancomycin
   OR
   (b) Documentation of inadequate treatment response, serious side effects, or non- susceptibility report for the current infection to Vancomycin
   OR
   (c) Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with Vancomycin
   OR
   (d) Request is for continuation of therapy that was started at an inpatient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER, DURATION OF THERAPY, START AND END DATE]

CONTINUATION OF THERAPY:
N/A: Each new infection treatment should be a new review

DURATION OF APPROVAL:
Initial authorization: Complicated skin and skin structure infections (cSSSI): 14 days
Hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP): 21 days
Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

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 infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous Infusion

DRUG CLASS:
Glycopeptides

FDA-APPROVED USES:
Indicated for the treatment of the following infections in adult patients caused by designated susceptible bacteria:
• Complicated skin and skin structure infections (cSSSI)

• Hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of Staphylococcus aureus. Vibativ should be reserved for use when alternative treatments are not suitable.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vibativ and other antibacterial drugs Vibativ should only be used to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Vibativ is indicated for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus), or Enterococcus faecalis (vancomycin susceptible isolates only).
Vibativ is indicated for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of Staphylococcus aureus (both methicillin-susceptible and -resistant isolates). Vibativ should be reserved for use when alternative treatments are not suitable.

COMPENDIAL APPROVED OFF-LABELED USES:
Bacteremia due to S. aureus (MRSA)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Vibativ (telavancin) is a parenteral lipoglycopeptide antibiotic. It has concentration-dependent bactericidal activity with dual mechanism of action - inhibition of synthesis of cell wall and disruption of bacterial cell membrane barrier. Vibativ is approved for treatment of complicated skin and skin structure infections due to Staph. aureus (MSSA, MRSA), Vancomycin-susceptible E. faecalis, and S. pyogenes, S. agalactiae, S. anginosus group. Vibativ is also approved for the treatment of adults with hospital-acquired and ventilator-associated pneumonia due to Staph. aureus (MSSA, MRSA). Telavancin was non-inferior to Vancomycin in a published study of hospital-acquired pneumonia that included MRSA pneumonia. Vibativ can be used as an alternative antibiotic for drug resistant pathogens.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vibativ (telavancin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Vibativ (telavancin) include: hypersensitivity to telavancin or any component of the formulation, concomitant use of intravenous unfractionated heparin sodium, avoid pregnancy.

OTHER SPECIAL CONSIDERATIONS:
Vibativ (telavancin) has a black box warning for increased mortality in HABP/VABP patients with pre-existing moderate or severe renal impairment, nephrotoxicity, and embryofetal toxicity.

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the flora of the colon and may permit overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hyper-toxin-producing strains of C. difficile cause increased morbidity and mortality, since these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not

directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

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
J3095	Injection, telavancin, 10mg

AVAILABLE DOSAGE FORMS:
Vibativ SOLR 750MG single-dose vial

REFERENCES

1. Vibativ (telavancin) for injection, for intravenous use [prescribing information]. Nashville, TN: Cumberland Pharmaceuticals Inc; November 2023.
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7. "Guidelines for the Management of Adults with Hospital-Acquired, Ventilator-Associated, and Healthcare-Associated Pneumonia." American Journal of Respiratory and Critical Care Medicine, vol. 171, no. 4, 2005, pp. 388–416., doi:10.1164/rccm.200405-644st.
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Diseases, 52(3). doi:10.1093/cid/ciq146
10. Stevens DL et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases.2014 Jul 15;56(2):e10-e52.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q1 2025
REVISION- Notable revisions: Required Medical Information Background	Q1 2024
REVISION- Notable revisions: Required Medical Information Drug Class FDA-Approved Uses Compendial Approved Off-Labeled Uses	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file