Vibativ (telavancin)
Policy Number: C14575-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
8/1/2018	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J3095-inj, telavancin, 10mg	RxPA	Q1 2021 20210127C14575-A

PRODUCTS AFFECTED:
Vibativ (telavancin)

DRUG CLASS:
Anti-Infective Agents - Misc.

ROUTE OF ADMINISTRATION:
Intravenous Infusion

PLACE OF SERVICE:
Buy and Bill, Specialty Pharmacy The recommendation is that medications in this policy will be for medical benefit coverage and administered in a place of service that is a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center)

AVAILABLE DOSAGE FORMS:
Vibativ Inj 250MG, Vibativ Inj 750MG

FDA-APPROVED USES:
VIBATIV is 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

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

COVERAGE CRITERIA: INITIAL AUTHORIZATION

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 (off-label)

REQUIRED MEDICAL INFORMATION:
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, intolerance, 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 a continuation of therapy that was started at an in-patient 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]

Based on the Infectious Diseases Society of America (IDSA) guidelines for the Treatment of Methicillin-Resistant Staphylococcus aureus (MRSA) Infections in Adults and Children, telavancin, as monotherapy or in combination with other agents, may be considered as an alternative agent for persistent bacteremia due to MRSA that has reduced susceptibility to vancomycin and daptomycin. Data from a small randomized, double-blind, phase 2 trial demonstrated utility for the treatment of uncomplicated S. aureus bacteremia (6)

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

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

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:
18 years of age or older

CONTINUATION OF THERAPY:
N/A

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

BLACK BOX WARNING: INCREASED MORTALITY IN HABP/VABP PATIENTS WITH PRE-EXISTING MODERATE OR SEVERE RENAL IMPAIRMENT, NEPHROTOXICITY, and EMBRYOFETAL TOXICITY

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
None

APPENDIX:
None

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, memberrecords, 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.

REFERENCES:

1. Vibativ (telavancin) [prescribing information]. Nashville, TN: Cumberland Pharmaceuticals Inc; December 2020
2. Stryjewski ME, O'Riordan WD, Lau WK, et al, "Telavancin Versus Standard Therapy for Treatment of Complicated Skin and Soft-Tissue Infections Due to Gram-Positive Bacteria," Clin Infect Dis, 2005, 40(11):1601-7
3. Rubinstein E, Lalani T, Corey GR, et al, "Telavancin versus Vancomycin for Hospital-Acquired Pneumonia Due to Gram-Positive Pathogens," Clin Infect Dis, 2011, 52(1):31-40.
4. Liu C, Bayer A, Cosgrove SE, et al, "Clinical Practice Guidelines by the Infectious Diseases Society of America for the Treatment of Methicillin-Resistant Staphylococcus Aureus Infections in Adults and Children: Executive Summary," Clin Infect Dis, 2011, 52(3):285-92.
5. Wilson SE, O'Riordan W, Hopkins A, et al, "Telavancin Versus Vancomycin for the Treatment of Complicated Skin and Skin-Structure Infections Associated With Surgical Procedures," Am J Surg, 2009, 197(6):791-6.
6. Stryjewski ME, Lentnek A, O'Riordan W, et al. A randomized Phase 2 trial of telavancin versus standard therapy in patients with uncomplicated Staphylococcus aureus bacteremia: the ASSURE study. BMC Infect Dis. 2014;14:289
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.