VIBATIV® (telavancin) Billing Guide

HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3095</td>
<td>Injection, telavancin 10 mg</td>
</tr>
<tr>
<td>CPT 96365</td>
<td>IV infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Formulation – 250 mg IV (vials)</th>
<th>Product Formulation – 750 mg IV (vials)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIBATIV NDC 52118-0002-01 or 62847-0002-01</td>
<td>VIBATIV NDC 52118-0001-01 or 62847-0001-01</td>
</tr>
</tbody>
</table>

Due to a legal name change (Theravance, Inc. to Theravance Biopharma, Inc.), each VIBATIV vial configuration will be available with new NDC numbers. Please refer to the NDC numbers listed above for billing and administrative purposes.

Theravance Biopharma Patient Assistance Program

For uninsured patients unable to afford VIBATIV
For more information and applications, please contact us at the following numbers:
Phone: 1-855-847-9435  Fax: 1-855-847-9478

Eligible patients must meet all of the following criteria:

- Be a legal resident of the United States or its territories
- Not be eligible for or have insurance coverage through any private or public insurance such as Medicare, Medicaid, Medicare prescription drug coverage, state-sponsored prescription drug assistance, employee, military, retirement, or pension-program drug coverage
- Meet the financial criteria established by the program

Please see VIBATIV BRIEF SUMMARY on the back. Additional information, including full Prescribing Information, can be found at www.VIBATIV.com.

THERAVANCE®, the Cross/Star logo, VIBATIV® and the VIBATIV logo are registered trademarks of the Theravance Biopharma group of companies.  VBT 00175-01  June 2016
VIBATIV® (telavancin) for injection, for intravenous use
Rx ONLY

INDICATIONS AND USAGE: VIBATIV® is a lipoglycopeptide antibiotic 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 (HAP/VAP) caused by susceptible isolates of Staphylococcus aureus. VIBATIV should be reserved for use when alternative treatments are not suitable.

CONTRAINdications:

- VIBATIV is contraindicated in patients who require intravenous unfractionated heparin sodium due to the potential of an artificially prolonged activated partial thromboplastin time resulting in adverse outcomes observed in animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans.

WARNINGS: INCREASED MORTALITY IN HABP/VAP PATIENTS WITH PRE-EXISTING MODERATE OR SEVERE RENAL IMPAIRMENT, NEPHROTOXICITY, POTENTIAL ADVERSE DEVELOPMENTAL OUTCOMES

- Patients with pre-existing moderate/severe renal impairment (CRI ≤ 50 mL/min) who were treated with VIBATIV for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HAP/VABP), had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CRI ≤ 50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

- Nephrotoxicity: New onset or worsening renal impairment has occurred. Monitor renal function in all patients.

- Women of childbearing potential should have a serum pregnancy test prior to initiating therapy with VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Potential developmental outcomes observed in animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans.

ADVERSE REACTIONS

In a subgroup analysis of the combined cSSSI clinical trials, serious adverse events were reported in 7% (69/929) of patients treated with VIBATIV and most commonly included renal, respiratory, or cardiac events. Serious adverse events were reported in 5% (43/838) of vancomycin-treated patients, and most commonly included cardiac or infectious events. Treatment discontinuations due to adverse events occurred in 8% (28/329) of patients treated with VIBATIV, the most common reasons being nausea, vomiting, and rash (~1% each). Treatment discontinuations due to adverse events occurred in 6% (53/838) of vancomycin-treated patients, the most common events being rash and pruritus (~1% each). The most common adverse events occurring in ≥10% of patients were gastrointestinal events (nausea, vomiting, and diarrhea) and rash (≥3% each). Drug-related rash or pruritus occurred in 7% (56/751) of VIBATIV recipients and 2% (20/938) of vancomycin recipients. VIBATIV recipients had a 2.3-fold increased risk of rash compared with vancomycin recipients. The most common non-drug-related adverse events occurring in ≥10% of patients were nausea, vomiting, and diarrhea (≥3% each). Drug-related nausea, vomiting, and diarrhea occurred in 15% (114/751) of VIBATIV recipients and 7% (67/938) of vancomycin recipients. In the analysis of patients (classified by the treatment received) in the two combined HABP/VABP trials with pre-existing moderate/severe renal impairment (CRI ≤ 50 mL/min), all-cause mortality within 28 days of starting treatment was 95/241 (39%) in the VIBATIV group, compared with 222/430 (52%) in the vancomycin group. All-cause mortality in patients without pre-existing moderate/severe renal impairment (CRI ≥ 50 mL/min) was 86/510 (17%) in the VIBATIV group and 92/510 (18%) in the vancomycin group. Therefore, VIBATIV use in patients with baseline CRI ≤ 50 mL/min should be considered only when the anticipated benefit to the patient outweighs the potential risk. Decreased Clinical Response in Patients with cSSSI and Pre-Existing Moderate/Severe Renal Impairment (CRI ≤ 50 mL/min): In a subgroup analysis of the combined cSSSI clinical trials, clinical cure rates in the VIBATIV-treated patients were lower in patients with baseline CRI ≤ 50 mL/min compared with those with CRI > 50 mL/min. A decrease of this magnitude was not observed in vancomycin-treated patients. Consider these data when selecting antibacterial therapy for use in patients with cSSSI and baseline moderate/severe renal impairment. Nephrotoxicity: In both the HABP/VAP trials and the cSSSI trials, renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction (pre-existing renal disease, diabetes mellitus, congestive heart failure, or hypertension). The renal adverse event rates were also higher in patients who received concomitant medication with potentially kidney function (e.g., non-steroidal anti-inflammatory drugs, ACE inhibitors, and loop diuretics). Monitor renal function (i.e., serum creatinine, creatinine clearance), particularly among patients receiving concomitant medications with potential organ toxicity. Values should be obtained prior to initiation and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV therapy should be reassessed with an alternative agent. Newborn System: Taste disturbance* occurred in 3% (77/2858) of patients treated with VIBATIV plus rifampin, compared with 2% (18/1002) of patients treated with vancomycin plus rifampin. Taste disturbance* occurred in 3% (30/929) of patients treated with VIBATIV, compared with 2% (18/938) of patients treated with vancomycin. taste disturbance* was reported in 3% (30/929) of patients treated with VIBATIV, compared with 2% (18/938) of patients treated with vancomycin. Taste disturbance* was also reported in 3% (30/929) of patients treated with VIBATIV, compared with 2% (18/938) of patients treated with vancomycin.

OVERDOSAGE: In the event of overdosage, VIBATIV should be discontinued and supportive care initiated. Any therapeutic benefit is unlikely since VIBATIV is a cephalosporin derivative of vancomycin; it is unknown if patients with hypersensitivity reactions to vancomycin will experience cross-reactivity to telavancin. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin. In case of severe/ life-threatening reactions, the patient should be treated intravenously with 0.5 mg/kg of anaphylaxis or anaphylactoid reactions, which may occur after first or subsequent doses. Discontinue VIBATIV and institute emergency therapy. Repeated use may result in hypotensive shock and anaphylaxis. In a study involving healthy volunteers, doses of 7.5 and 15 mg/kg of VIBATIV prolonged the QTc interval. Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. Patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy are not included in clinical trials of VIBATIV. Use of VIBATIV should be avoided in these patients.

In HABP/VAP clinical trials, serious adverse events were reported in 31% of patients treated with VIBATIV and 26% of patients who received vancomycin. Treatment discontinuations due to adverse events occurred in 8% (67/805) of patients who received VIBATIV, the most common events being nausea and vomiting (~1% each). Treatment discontinuations due to adverse events occurred in 6% (52/848) of vancomycin-treated patients, the most common events being rash and pruritus (~1% each). The most common serious adverse event occurring in ≥10% of patients with baseline moderate/severe renal impairment was acute renal failure (N=53/751). The renal adverse event rate was higher in patients who received vancomycin (N=41/751) compared with those who received VIBATIV (N=42/751). The most common non-drug-related adverse event occurring in ≥10% of patients with baseline moderate/severe renal impairment was acute renal failure (N=42/751) compared with those who received VIBATIV (N=42/751). The renal adverse event rate was higher in patients who received vancomycin (N=41/751) compared with those who received VIBATIV (N=42/751). The most common non-drug-related adverse event occurring in ≥10% of patients with baseline moderate/severe renal impairment was acute renal failure (N=42/751) compared with those who received VIBATIV (N=42/751). The renal adverse event rate was higher in patients who received vancomycin (N=41/751) compared with those who received VIBATIV (N=42/751). The most common non-drug-related adverse event occurring in ≥10% of patients with baseline moderate/severe renal impairment was acute renal failure (N=42/751) compared with those who received VIBATIV (N=42/751). The renal adverse event rate was higher in patients who received vancomycin (N=41/751) compared with those who received VIBATIV (N=42/751).