

FIRST QUARTER 2010 CODING AND BILLING REFERENCE SHEET (1/1/10-3/31/10)



Appropriate and accurate coding is important for healthcare providers to receive appropriate reimbursement for drug therapies like VIBATIV. Coding should reflect services provided to the patient as documented in the patient's medical record.

Medicare uses the Medicare Physician Fee Schedule (MPFS) to pay for services provided to patients in the office/freestanding infusion center setting. Medicare adjusts payment for procedures (but not for drugs) based on the geographic location of the physician. For specific payment levels in your area, go to www.cms.hhs.gov/PFSlookup/.

Medicare bases payment for hospital outpatient facilities on Ambulatory Payment Classifications (APCs). Procedures that share similar clinical characteristics and are similar in terms of cost requirements are grouped together into an APC. Medicare assigns to each APC group a payment amount that is made to the hospital. Hospital outpatient payments for procedures (but not for drugs) are subject to geographic adjustments.

CPT Codes ¹	Description	2010 Medicare Payment			
		Physician Office/ Freestanding Infusion Center	Hospital Outpatient		
			MPFS ² (Unadjusted Payment Amount) ³	APC	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	\$66.76	0439	Level IV Drug Administration	\$126.78
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	\$20.57	0436	Level I Drug Administration	\$25.67

¹The Defense Appropriations Act freezes payment rates at the 2009 level for dates of service from January 1, 2010 through February 28, 2010. Absent Congressional intervention, effective March 1, 2010, payment rates will decrease by 21.2%.

Medicare's reimbursement mechanism for new drugs like VIBATIV varies according to the setting of care.

In the physician office or freestanding infusion settings, new drugs are reimbursed at Wholesale Acquisition Price (WAC) +6% until sufficient Average Sales Price (ASP) data are available, which can take from six to nine months after a product becomes available.

In the hospital outpatient setting, new drugs initially are reimbursed at 95% of Average Wholesale Price (AWP) while billed with C9399. Once a new drug receives a temporary, drug-specific C-code (for use on Medicare hospital outpatient claims only), reimbursement will transition to WAC +6% until adequate ASP data are available.

Setting of Care	HCPCS Code	Q1 2010 Medicare Payment
Physician Office/Freestanding Infusion Center	J3490 , unclassified drug	250-mg vial (NDC 00469-3525-30): \$53.00
Physician Office/Freestanding Infusion Center	J3490 , unclassified drug	750-mg vial (NDC 00469-3575-50): \$159.00
Hospital Outpatient Department	C9399 , unclassified drug or biologic	250-mg vial (NDC 00469-3525-30): \$57.00
Hospital Outpatient Department	C9399 , unclassified drug or biologic	750-mg vial (NDC 00469-3575-50): \$171.00

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by ARS are to assist healthcare providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider. Information provided should in no way be considered a guarantee of coverage or reimbursement for any product or service.

1. *Current Procedural Terminology (CPT), Professional Edition, 2010.* American Medical Association, 2009. All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no responsibility for the data contained herein. CPT is a registered trademark of the American Medical Association. **2.** 42 CFR Parts 410, 411, et al. Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Final Rule, November 25, 2009: 61738, 62136; Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, Corrections. *Federal Register*, December 10, 2009; Department of Defense Appropriations Act, 2010, Pub. L. no. 111-118, Sec. 1011. 2010 Unadjusted MPFS Payment: calculated using the following formula: Transitioned Non-Facility Total * 2010 Conversion Factor of \$36.0846, as per the Defense Appropriations Act, which freezes payment rates at the 2009 level for dates of service from January 1, 2010 through February 28, 2010. Absent Congressional intervention, effective March 1, 2010, the conversion factor will decrease to 28.3895. **3.** 42 CFR Parts 410, 416, and 419. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule, November 20, 2009: 60852.

PLEASE SEE FULL PRESCRIBING INFORMATION AND MEDICATION GUIDE IN THE PRODUCT INFORMATION SECTION.

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VIBATIV is indicated for:

- 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*)
 - *Enterococcus faecalis* (vancomycin-susceptible isolates only)

Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative organisms.

Important Safety Information

Fetal Risk

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

If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

Nephrotoxicity

New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCl ≤ 50 mL/min compared to those with CrCl > 50 mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment.

Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion-Related Reactions

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome"-like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

Clostridium difficile-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use.

Development of Drug-Resistant Bacteria

Prescribing VIBATIV in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antibacterial drugs, use of VIBATIV may result in overgrowth of nonsusceptible organisms, including fungi.

QTc Prolongation

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Coagulation Test Interference

VIBATIV does not interfere with coagulation, but does interfere with certain tests used to monitor coagulation such as prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and coagulation based factor Xa tests. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV.

Adverse Reactions

The most common adverse reactions ($\geq 10\%$ of patients treated with VIBATIV) observed in the Phase III cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase III cSSSI clinical trials, serious adverse events were reported in 7% of patients treated with VIBATIV and most commonly included renal, respiratory, or cardiac events. In the same trials, serious adverse events were reported in 5% of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events. Eight deaths were reported in each treatment group.