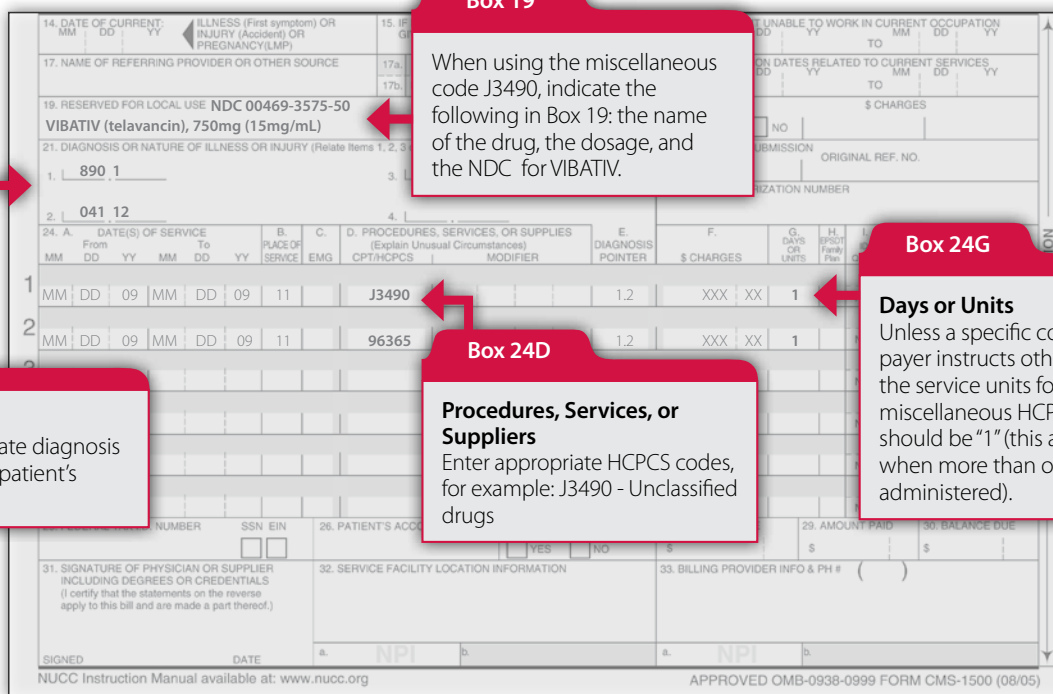


## MISCELLANEOUS CODING & BILLING REFERENCE SHEET

### FIRST COAST SERVICE OPTIONS



**Medicare Administrative Contractor (MAC) Jurisdiction 9  
(MAC for FL, PR, US VI)  
Freestanding Infusion Center/Physician Office Setting (Part B)- CMS-1500**



**Box 19**  
When using the miscellaneous code J3490, indicate the following in Box 19: the name of the drug, the dosage, and the NDC for VIBATIV.

**Box 21**  
**Diagnosis Code**  
Enter the appropriate diagnosis as reflected in the patient's medical record.

**Box 24D**  
**Procedures, Services, or Suppliers**  
Enter appropriate HCPCS codes, for example: J3490 - Unclassified drugs

**Box 24G**  
**Days or Units**  
Unless a specific contractor/payer instructs otherwise, the service units for the miscellaneous HCPCS codes should be "1" (this applies even when more than one vial is administered).

#### Tips for billing miscellaneous codes when filing claims with First Coast Service Options

- ▶ When using the miscellaneous code J3490, indicate in Box 19 of the CMS-1500 form (or its electronic equivalent):
  - The name of the drug
  - The total dosage
  - The NDC
- ▶ Include a concise description of the drug in Box 19 or otherwise send an attachment with the claim that provides additional description of the drug. An attachment may help to expedite claims processing.
  - A description may include such information as the method of drug administration, the National Drug Code, etc.
- ▶ Offices submitting electronic claims should check with their respective software vendor to identify if there are any character limits associated with Box 19 or its electronic equivalent. You may need to shorten the description in Box 19, as appropriate, if character limits apply.
- ▶ Please note First Coast Service Options requires ICD-9-CM codes for both the type of infection AND the site of infection.

Effective 4/1/10-6/30/10, the Medicare payment rate in the freestanding infusion center/physician office setting is Wholesale Acquisition Cost (WAC)+6% until average sales price (ASP) has been established.

• Newly FDA-approved drugs without sales data are reimbursed by Medicare at WAC+6% in the freestanding infusion center/physician office, until ASP is established. Once the ASP is determined, VIBATIV will be reimbursed at ASP+6% in the freestanding infusion center/physician office setting

**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.

This information is accurate as of 4/1/10 and is subject to change at any time due to contractor discretion. Contact your ARS representative to confirm current guidance.

**Astellas Reimbursement Services<sup>SM</sup>**  
Phone: 1-800-477-6472  
Fax: 1-866-317-6235  
Monday-Friday, 9 AM to 8 PM ET  
[www.astellasreimbursement.com](http://www.astellasreimbursement.com)

**PLEASE SEE INDICATION AND IMPORTANT SAFETY INFORMATION ON REVERSE.**

**PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION AND MEDICATION GUIDE.**



Astellas Reimbursement Services<sup>SM</sup>

**MISCELLANEOUS CODING & BILLING REFERENCE SHEET****FIRST COAST SERVICE OPTIONS**

**Medicare Administrative Contractor (MAC) Jurisdiction 9  
(MAC for FL, PR, US VI)  
Freestanding Infusion Center/Physician Office Setting (Part B)- CMS-1500**

**INDICATION:**

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).

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

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to telavancin. VIBATIV may be initiated as empiric therapy before results of these tests are known. To reduce the development of drug-resistant bacteria and maintain the effectiveness of VIBATIV and other antibacterial drugs, VIBATIV should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**IMPORTANT SAFETY INFORMATION**

**Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid the use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse fetal 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.

New onset or worsening renal impairment has occurred in patients who received VIBATIV. In clinical trials 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. Renal function should be monitored in all patients receiving VIBATIV. Lower clinical response rates may occur in patients with moderate/severe renal impairment. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions, ie, “Red-man Syndrome”-like reactions.

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

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. Patients should be carefully monitored during therapy.

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT 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.

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.

In clinical trials comparing VIBATIV with vancomycin, Adverse reactions reported in more than 10% of patients treated with VIBATIV included: taste disturbance, nausea, vomiting, and foamy urine. Serious adverse events were reported in 7% of patients treated with VIBATIV and most commonly included renal, respiratory, or cardiac events. 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.



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