Theravance Biopharma VIBATIV® (telavancin) Coding and Billing Guide

Indication:

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* (including methicillin-susceptible and -resistant isolates). VIBATIV should be reserved for use when alternative treatments are not suitable.

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)

Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at www.VIBATIV.com.

Theravance® Biopharma
Medicines That Make a Difference®

VIBATIV®
(telavancin) for injection

Introduction

The VIBATIV Coding and Billing Guide was developed to help healthcare providers and billing staff understand third-party payor coding and billing requirements for VIBATIV. This guide presents general information on the coverage, coding, and claims submission for VIBATIV to third-party payors. The information contained in this guide is intended to provide general information related to coding and billing and should not be used to assist healthcare providers and billing staff in obtaining reimbursement for any specific patient claim.

Access VIBATIV Reimbursement Support

Additional information about VIBATIV coding, billing, and coverage may be obtained through Access VIBATIV reimbursement program at: **1.855.847.9435**. Access VIBATIV is available Monday through Friday excluding holidays, 8 AM to 7 PM Central Time.

Coding for VIBATIV

It is important for health care providers and billing staff to accurately and fully complete claim forms for VIBATIV, whether the claim is submitted by physician offices or infusion centers. This guide identifies procedure and product codes that are likely to be most relevant to healthcare provider claims for VIBATIV. Please note that healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition and the items and services that are furnished during that patient encounter. Contact the appropriate payor with regard to local coverage policies.

Coverage for VIBATIV

Third-party payors (e.g., commercial insurance, Medicare, Medicaid, etc.) should cover VIBATIV for its approved U.S. Food and Drug Administration indications. Specific payor coverage and benefits, however, may vary based on a patient's insurer or specific insurance plan or insurance product (i.e., HMO, PPO, Indemnity, other) offered by a payor.

When reviewing claims for VIBATIV, third-party payors will first determine if the reported service may be covered under their coverage policies or contract with the health care provider. Most payors cover drug infusions provided under the supervision of a physician as part of their medical benefits. In addition, some payors may look for evidence supporting the medical necessity of VIBATIV. This evidence may sometimes include:

- Prescribing information
- Physician's statement or letter of medical necessity
- Information about the patient's medical condition and history

There may be other general administrative policies that also affect coverage of VIBATIV therapy. For example, many payors may consider the following when making coverage decisions:

A Prior Authorization may be required by the patient's insurance plan

Many commercial plans, as well as Medicaid, may require that non-emergency services be pre-approved through a Prior Authorization process prior to the administration of VIBATIV. Failure to obtain appropriate Prior Authorization may result in nonpayment of VIBATIV and associated services by the plan. Medicare fee for service (Part B) generally does not require a Prior Authorization for services.

The patient's health plan may restrict coverage of VIBATIV when provided in certain settings

Payors may have site-specific coverage rules that restrict provision of infused antibiotics. For example, Medicare may restrict coverage for infused therapies in the home setting under Medicare Part B.

Coding and Billing Checklist

In order to minimize claims denials and delayed payments, it may be helpful to perform a prebilling review prior to submitting any claim to a payor. The following may be considered in the prebilling review:

- ❑ Has patient insurance coverage been verified?
- ❑ Is this service covered by patient insurance?
- ❑ Have the specific payor billing requirements been followed?
- ❑ Was a Prior Authorization needed and obtained for this treatment?
- ❑ Depending on insurance coverage, is the referral authorized?
- ❑ Has medical necessity been documented?
- ❑ Has all of the required encounter information been included on the claim?
- ❑ Have the correct codes (diagnosis, CPT, and HCPCS) been reported?
- ❑ Have the billed units been entered accurately and consistently with the J-code description?
- ❑ If a separate and distinct E/M service was provided, has it been identified with modifier -25?

Appeals Checklist

The most common reason for denials or underpayments of claims include:

- ❑ Omission of any information that clarifies medical necessity (e.g. relevant diagnosis codes)
- ❑ Inaccurately reporting the billable units of drug (note that VIBATIV is reported in 10 mg increments)
- ❑ Use of incorrect CPT or HCPCS codes (note that VIBATIV is reported using HCPCS J3095 telavancin 10 mg)
- ❑ Failure to follow payor-specific requirements for providing this therapy, including referrals and Prior Authorization
- ❑ Lack of proper and complete documentation for patient encounter
- ❑ Omission of special coding requirements (e.g. the NDC number or required modifiers)
- ❑ In certain cases, omission of a physician letter/statement of medical necessity

Different payors provide different appeals rights depending upon the level of appeal for the denied claim (e.g. first appeal, second appeal). In the event of a claim denial, be sure to resubmit your claim. Most well-documented follow-up submissions are successful.

VIBATIV Product Coding Information

HCPCS Code	Description	Billing Units
J3095	Injection, telavancin, 10 mg	75 units per 750 mg vial

NDC	Description
62847-0001-01	VIBATIV Intravenous Solution Reconstituted 750 mg

Infusion Procedure Information

CPT Procedure Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour

Billing for Wastage

Physicians and hospitals are expected to schedule patients in such a way that they can use drugs most efficiently, in a clinically appropriate manner. Drug wastage may be documented in the patient's medical record with the date, time, amount wasted, and reason for wastage. Each payor may have different policies regarding drug wastage and may require physicians and hospitals to include the amount of product administered and the amount discarded when line-item billing VIBATIV. It is recommended to verify the drug wastage requirements of the specific health plan. Finally, some payors request that physicians and hospitals identify any discarded product by appending the –JW modifier to the claim.

Common Diagnosis Codes for VIBATIV

Indication	ICD-10-CM Diagnosis Code	Description
cSSSI	H05.011	Cellulitis of right orbit
	H05.012	Cellulitis of left orbit
	H05.013	Cellulitis of bilateral orbits
	H05.019	Cellulitis of unspecified orbit
	H60.10	Cellulitis of external ear, unspecified ear
	H60.11	Cellulitis of right external ear
	H60.12	Cellulitis of left external ear
	H60.13	Cellulitis of external ear, bilateral
	K12.2	Cellulitis and abscess of mouth
	L03.011	Cellulitis of right finger
	L03.012	Cellulitis of left finger
	L03.019	Cellulitis of unspecified finger
	L03.031	Cellulitis of right toe
	L03.032	Cellulitis of left toe
	L03.039	Cellulitis of unspecified toe
	L03.111	Cellulitis of right axilla
	L03.112	Cellulitis of left axilla
	L03.113	Cellulitis of right upper limb
	L03.114	Cellulitis of left upper limb
	L03.115	Cellulitis of right lower limb
	L03.116	Cellulitis of left lower limb
	L03.119	Cellulitis of unspecified part of limb
	L03.211	Cellulitis of face
	L03.213	Periorbital cellulitis
	L03.221	Cellulitis of neck
	L03.311	Cellulitis of abdominal wall
	L03.312	Cellulitis of back [any part except buttock]
	L03.313	Cellulitis of chest wall
	L03.314	Cellulitis of groin

Common Diagnosis Codes for VIBATIV (continued)

Indication	ICD-10-CM Diagnosis Code	Description
cSSSI (continued)	L03.315	Cellulitis of perineum
	L03.316	Cellulitis of umbilicus
	L03.317	Cellulitis of buttock
	L03.319	Cellulitis of trunk, unspecified
	L03.811	Cellulitis of head [any part, except face]
	L03.818	Cellulitis of other sites
	L03.90	Cellulitis, unspecified
	L08.89	Other specified local infections of the skin and subcutaneous tissue
	L08.9	Local infection of the skin and subcutaneous tissue, unspecified
	N48.22	Cellulitis of corpus cavernosum and penis
Abscess	H00.031	Abscess of right upper eyelid
	H00.032	Abscess of right lower eyelid
	H00.033	Abscess of eyelid right eye, unspecified eyelid
	H00.034	Abscess of left upper eyelid
	H00.035	Abscess of left lower eyelid
	H00.036	Abscess of eyelid left eye, unspecified eyelid
	H00.039	Abscess of eyelid unspecified eye, unspecified eyelid
	H60.00	Abscess of external ear, unspecified ear
	H60.01	Abscess of right external ear
	H60.02	Abscess of left external ear
	H60.03	Abscess of external ear, bilateral
	J34.0	Abscess, furuncle and carbuncle of nose
	K61.0	Anal abscess
	K61.1	Rectal abscess
	K61.2	Anorectal abscess
	K61.3	Ischiorectal abscess
	K61.4	Intrasphincteric abscess
	L02.01	Cutaneous abscess of face
	L02.11	Cutaneous abscess of neck

Common Diagnosis Codes for VIBATIV (continued)

Indication	ICD-10-CM Diagnosis Code	Description
Abscess (continued)	L02.211	Cutaneous abscess of abdominal wall
	L02.212	Cutaneous abscess of back [any part, except buttock]
	L02.213	Cutaneous abscess of chest wall
	L02.214	Cutaneous abscess of groin
	L02.215	Cutaneous abscess of perineum
	L02.216	Cutaneous abscess of umbilicus
	L02.219	Cutaneous abscess of trunk, unspecified
	L02.31	Cutaneous abscess of buttock
	L02.411	Cutaneous abscess of right axilla
	L02.412	Cutaneous abscess of left axilla
	L02.413	Cutaneous abscess of right upper limb
	L02.414	Cutaneous abscess of left upper limb
	L02.415	Cutaneous abscess of right lower limb
	L02.416	Cutaneous abscess of left lower limb
	L02.419	Cutaneous abscess of limb, unspecified
	L02.511	Cutaneous abscess of right hand
	L02.512	Cutaneous abscess of left hand
	L02.519	Cutaneous abscess of unspecified hand
	L02.611	Cutaneous abscess of right foot
	L02.612	Cutaneous abscess of left foot
	L02.619	Cutaneous abscess of unspecified foot
	L02.811	Cutaneous abscess of head [any part, except face]
	L02.818	Cutaneous abscess of other sites
	L02.91	Cutaneous abscess, unspecified
Carbuncle	L02.03	Carbuncle of face
	L02.13	Carbuncle of neck
	L02.231	Carbuncle of abdominal wall
	L02.232	Carbuncle of back [any part, except buttock]
	L02.233	Carbuncle of chest wall

Common Diagnosis Codes for VIBATIV (continued)

Indication	ICD-10-CM Diagnosis Code	Description
Carbuncle (continued)	L02.234	Carbuncle of groin
	L02.235	Carbuncle of perineum
	L02.236	Carbuncle of umbilicus
	L02.239	Carbuncle of trunk, unspecified
	L02.33	Carbuncle of buttock
	L02.431	Carbuncle of right axilla
	L02.432	Carbuncle of left axilla
	L02.433	Carbuncle of right upper limb
	L02.434	Carbuncle of left upper limb
	L02.435	Carbuncle of right lower limb
	L02.436	Carbuncle of left lower limb
	L02.439	Carbuncle of limb, unspecified
	L02.531	Carbuncle of right hand
	L02.532	Carbuncle of left hand
	L02.539	Carbuncle of unspecified hand
	L02.631	Carbuncle of right foot
	L02.632	Carbuncle of left foot
	L02.639	Carbuncle of unspecified foot
	L02.831	Carbuncle of head [any part, except face]
	L02.838	Carbuncle of other sites
	L02.93	Carbuncle, unspecified
Furuncle	L02.02	Furuncle of face
	L02.12	Furuncle of neck
	L02.221	Furuncle of abdominal wall
	L02.222	Furuncle of back [any part, except buttock]
	L02.223	Furuncle of chest wall
	L02.224	Furuncle of groin
	L02.225	Furuncle of perineum
	L02.226	Furuncle of umbilicus

Common Diagnosis Codes for VIBATIV (continued)

Indication	ICD-10-CM Diagnosis Code	Description
Furuncle (continued)	L02.229	Furuncle of trunk, unspecified
	L02.32	Furuncle of buttock
	L02.421	Furuncle of right axilla
	L02.422	Furuncle of left axilla
	L02.423	Furuncle of right upper limb
	L02.424	Furuncle of left upper limb
	L02.425	Furuncle of right lower limb
	L02.426	Furuncle of left lower limb
	L02.429	Furuncle of limb, unspecified
	L02.521	Furuncle right hand
	L02.522	Furuncle left hand
	L02.529	Furuncle unspecified hand
	L02.621	Furuncle of right foot
	L02.622	Furuncle of left foot
	L02.629	Furuncle of unspecified foot
	L02.821	Furuncle of head [any part, except face]
	L02.828	Furuncle of other sites
	L02.92	Furuncle, unspecified
HABP/VABP	J15.20	Pneumonia due to staphylococcus, unspecified
	J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
	J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
	J15.29	Pneumonia due to other staphylococcus
	J95.851	Ventilator associated pneumonia
Methicillin-resistant Staphylococcus aureus	A41.02	Sepsis due to Methicillin resistant *Staphylococcus aureus*
	A49.02	Methicillin resistant *Staphylococcus aureus* infection, unspecified site
	B95.62	Methicillin resistant *Staphylococcus aureus* infection as the cause of diseases classified elsewhere
Staphylococcus	A41.01	Sepsis due to Methicillin susceptible *Staphylococcus aureus*
	A41.1	Sepsis due to other specified staphylococcus
	A41.2	Sepsis due to unspecified staphylococcus

Common Diagnosis Codes for VIBATIV (continued)

Indication	ICD-10-CM Diagnosis Code	Description
Staphylococcus (continued)	A49.01	Methicillin susceptible Staphylococcus aureus infection, unspecified site
	B95.5	Unspecified streptococcus as the cause of diseases classified elsewhere
	B95.61	Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere
	B95.7	Other staphylococcus as the cause of diseases classified elsewhere
	B95.8	Unspecified staphylococcus as the cause of diseases classified elsewhere
Streptococcus	A40.0	Sepsis due to streptococcus, group A
	A40.1	Sepsis due to streptococcus, group B
	A40.3	Sepsis due to Streptococcus pneumoniae
	A40.8	Other streptococcal sepsis
	A40.9	Streptococcal sepsis, unspecified
	A49.1	Streptococcal infection, unspecified site
	B95.0	Streptococcus, group A, as the cause of diseases classified elsewhere
	B95.1	Streptococcus, group B, as the cause of diseases classified elsewhere
	B95.3	Streptococcus pneumoniae as the cause of diseases classified elsewhere
	B95.4	Other streptococcus as the cause of diseases classified elsewhere
Other	B95.2	Enterococcus as the cause of diseases classified elsewhere
	L08.0	Pyoderma

CODING DISCLAIMER

THIS IS NOT AN ALL-INCLUSIVE LIST; CONSULT WITH PAYOR TO OBTAIN SPECIFIC COVERAGE POLICIES AND REQUIREMENTS FOR COVERED INDICATIONS

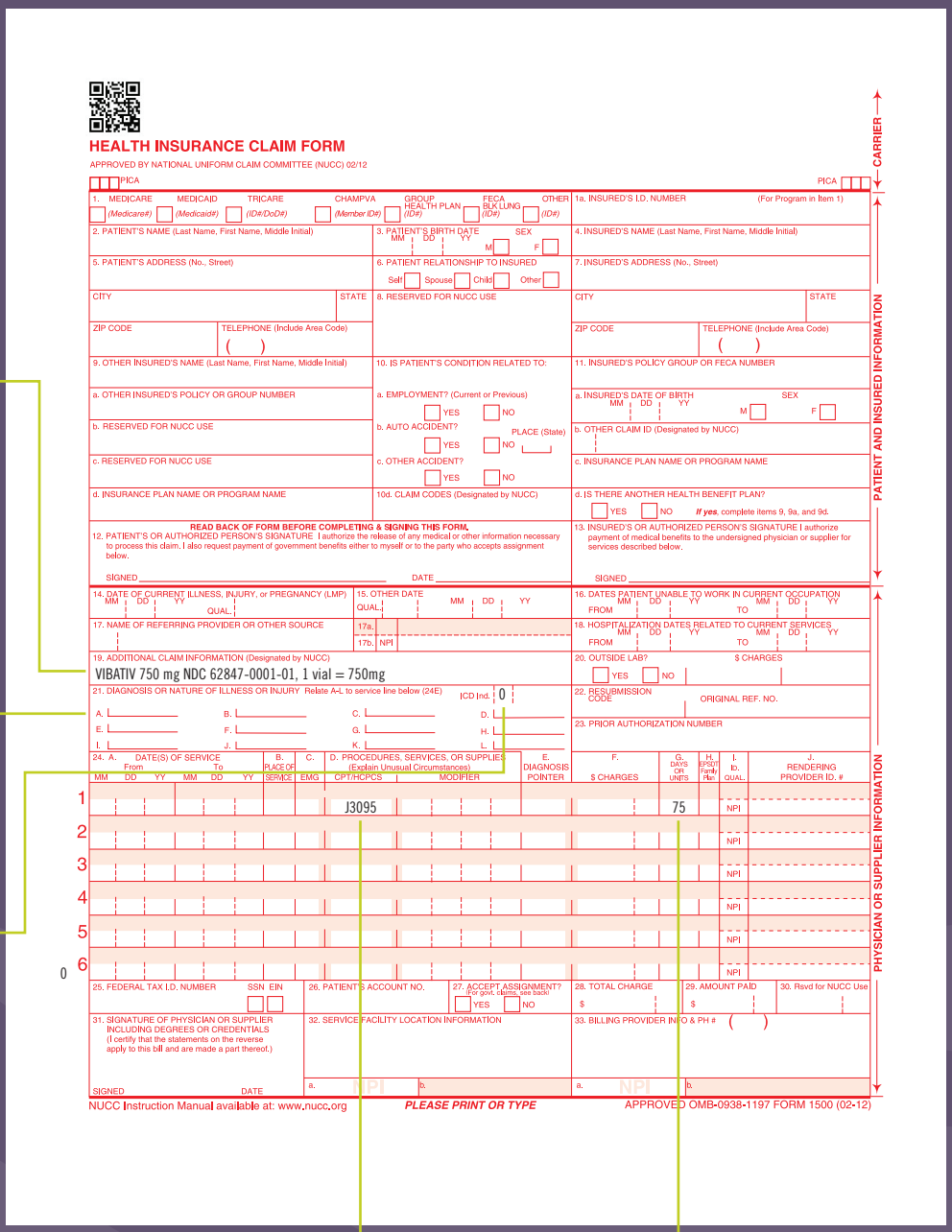
For additional information regarding coding, coverage, and reimbursement policies or claim denials for VIBATIV, the Access VIBATIV support program provides a single source of services designed to simplify access to therapy with VIBATIV at **1.855.847.9435**, Monday through Friday excluding holidays, 8 AM to 7 PM CT.

The information in this guide is provided to assist you in understanding the reimbursement process. It is intended to help providers in accurately obtaining reimbursement for healthcare services. It is not intended to increase or maximize reimbursement by any payor. We strongly suggest that you consult your payor organization with regard to local reimbursement policies. This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. While Theravance Biopharma has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Please consult with your reimbursement specialist for any reimbursement or billing questions. Similarly, all Current Procedural Terminology (CPT®) & Healthcare Common Procedure Coding System (HCPCS) billing codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Theravance Biopharma that these codes will be appropriate or that reimbursement will be made.

Sample CMS 1500 Billing Form

For service performed in physician offices

This document is provided for informational purposes only.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

VIBATIV 750 mg NDC 62847-0001-01, 1 vial = 750mg

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1				J3095				75			NPI
2											NPI
3											NPI
4											NPI
5											NPI
0 6											NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Box 19: Additional Information

Enter the appropriate drug identifying information as required by payor, e.g. brand and generic drug name, NDC code in 11 digit format, dosage, method of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payor.

Box 21: Diagnosis

Enter the appropriate ICD-10-CM diagnosis code. Final code depends on medical record documentation.

Box 21: ICD Indicator

Identify the type of ICD diagnosis code used, e.g. enter "0" for ICD-10-CM.

Box 24 D: Procedures, services, or suppliers

Enter the appropriate CPT/HCPS codes and modifiers, e.g.:

- Drug J3095 for VIBATIV
- 96365 First hour IV infusion

Box 24 G: Units

Enter the appropriate number of units of service. VIBATIV is typically billed in the physician office setting on a "per 10 mg basis."

Example: Full dose of VIBATIV may be equal to 75 units of J3095 (750mg)

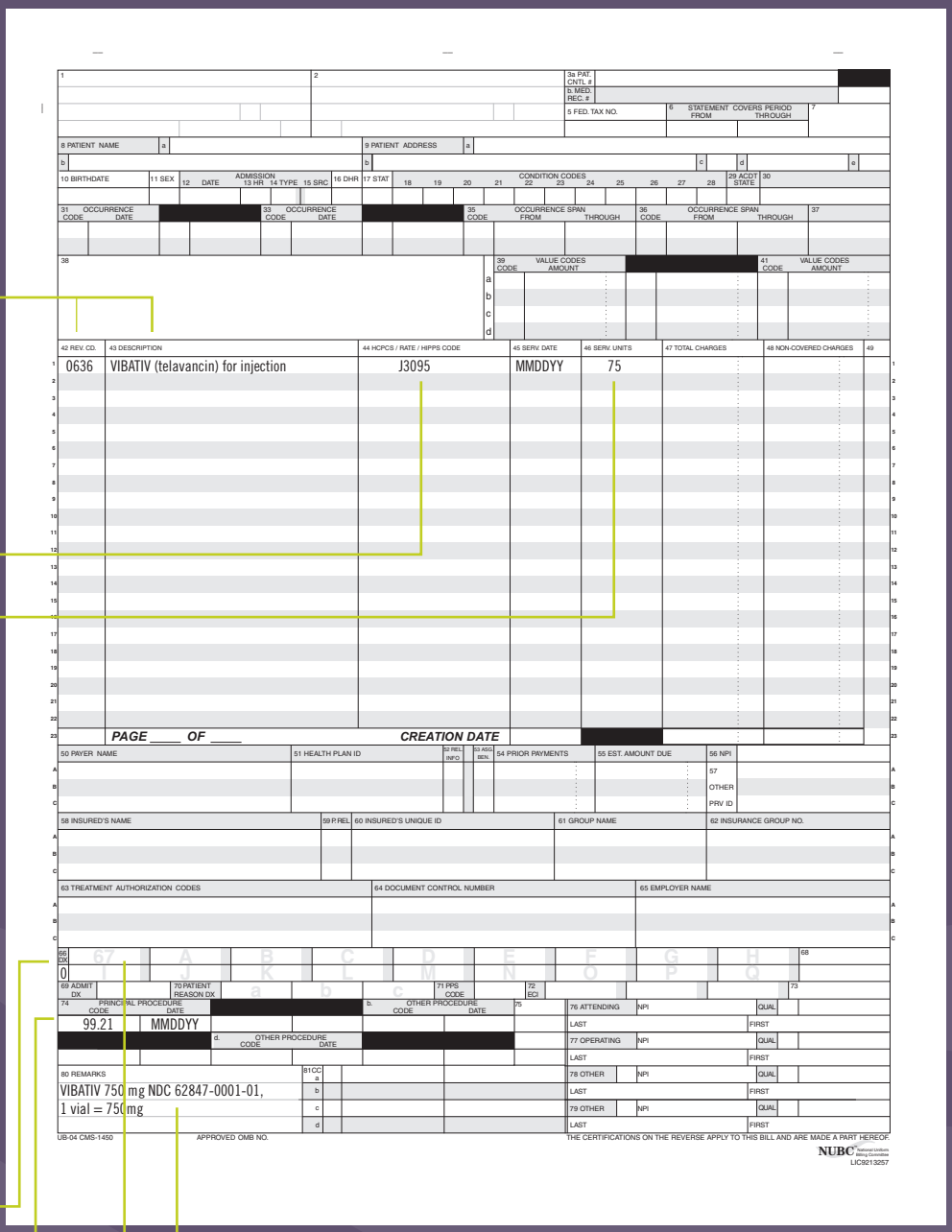
Note: Some payors may provide alternate guidance.

Please see Indication and Important Safety Information on last page.

Sample CMS 1450 Billing Form

For service performed in the hospital

This document is provided for informational purposes only.



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0636	VIBATIV (telavancin) for injection	J3095	MMDDYY	75		

PAGE ____ OF ____ CREATION DATE

66 DX: 0

74 PRINCIPAL PROCEDURE CODE: 99.21 DATE: MMDDYY

80 REMARKS: VIBATIV 750 mg NDC 62847-0001-01, 1 vial = 750mg

UB-04 CMS-1450 APPROVED OMB NO. THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

NUBC National Uniform Billing Committee

LIC9213257

Fields 42-43: Enter the appropriate code and description corresponding to the HCPCS code in field 44, e.g.:

- 0636 for VIBATIV
- 0510 for IV infusion administration in the clinic

Note: Other revenue codes may apply.

Field 44: Enter appropriate CPT/HCPCS codes and modifiers, e.g.:

- J3095 is the code designated HCPCS for patients in the hospital outpatient setting
- 96365 for first hour of IV infusion

Field 46: Report the appropriate unit of service. VIBATIV is typically billed in the hospital outpatient setting on a "per 10 mg basis." *However, some payors may provide alternate guidance*, e.g. A full course of VIBATIV is equal to 75 units of J3095 (10mg)

Field 66: Identify the type of ICD diagnosis code used, e.g. enter a "0" for ICD-10-CM.

Field 74: Enter ICD-10-CM procedure code for treatment in the hospital inpatient setting, e.g. 3E03329 introduction of other anti-infective into peripheral vein, percutaneous approach.

Enter principal ICD-9-CM procedure code for treatment in the hospital outpatient setting, e.g. 99.21 for injection of Antibiotic.

Field 67: Enter the appropriate diagnosis code

Field 80: Enter the appropriate drug identifying information as required by payor, e.g. brand and generic name, NDC code in 11 digit format, dosage, method of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payor.

Please see Indication and Important Safety Information on last page.

VIBATIV®
(telavancin) for injection

VIBATIV® (telavancin) for injection, for intravenous use

Rx ONLY

BRIEF SUMMARY. See package insert available at www.vibativ.com for full Prescribing Information, including Boxed Warning and Medication Guide.

INDICATIONS AND USAGE: VIBATIV is a lipoglycopeptide antibacterial drug 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.

CONTRAINDICATIONS:

- VIBATIV is contraindicated in patients who require intravenous unfractionated heparin sodium due to the potential of an artificially prolonged activated partial thromboplastin time (aPTT) up to 18 hours after VIBATIV administration.
- VIBATIV is contraindicated in patients with known hypersensitivity to telavancin.

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

- **Patients with pre-existing moderate/severe renal impairment (CrCl ≤ 50 mL/min) who were treated with VIBATIV for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl ≤ 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 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 3 animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans.**

WARNINGS AND PRECAUTIONS: Increased Mortality in Patients with HABP/VABP and Pre-existing Moderate to Severe Renal Impairment (CrCl ≤50 mL/min): In the analysis of patients (classified by the treatment received) in the two combined HABP/VABP trials with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min), all-cause mortality within 28 days of starting treatment was 95/241 (39%) in the VIBATIV group, compared with 72/243 (30%) in the vancomycin group. All-cause mortality at 28 days in patients without pre-existing moderate/severe renal impairment (CrCl >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 CrCl ≤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 (CrCl ≤50 mL/min):** In a subgroup analysis of the combined cSSSI trials, clinical cure rates in the VIBATIV-treated patients were lower in patients with baseline CrCl ≤50 mL/min compared with those with CrCl >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 with baseline moderate/severe renal impairment. **Nephrotoxicity:** In both the HABP/VABP 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 medications known to affect kidney function (e.g., non-steroidal anti-inflammatory drugs, ACE inhibitors, and loop diuretics). Monitor renal function (i.e., serum creatinine, creatinine clearance) in all patients receiving VIBATIV. Values should be obtained prior to initiation of treatment, during treatment (at 48- to 72-hour intervals or more frequently, if clinically indicated), 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. In patients with renal dysfunction, accumulation of the solubilizer hydroxypropyl-betacyclodextrin can occur. **Pregnant Women and Women of Childbearing Potential:** Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. VIBATIV caused adverse developmental outcomes in 3 animal species at clinically relevant doses. This raises concern about potential adverse developmental outcomes in humans. Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment. **Coagulation Test Interference:** Although telavancin does not interfere with coagulation, it interfered with certain tests used to monitor coagulation, when conducted using samples drawn 0 to 18 hours after VIBATIV administration for patients being treated once every 24 hours. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV. Blood samples for coagulation tests unaffected by VIBATIV may be collected at any time. No evidence of increased bleeding risk has been observed in clinical trials with VIBATIV. Telavancin has no effect on platelet aggregation. Furthermore, no evidence of hypercoagulability has been seen, as healthy subjects receiving VIBATIV have normal levels of D-dimer and fibrin degradation products. **Hypersensitivity Reactions:** Serious and sometimes fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. Discontinue VIBATIV at first sign of skin rash, or any other sign of hypersensitivity. Telavancin is a semi-synthetic 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. **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. Stopping or slowing the infusion may result in cessation of these reactions. ***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. 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. Hypertoxin-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. **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. Patients should be carefully monitored during therapy. If superinfection occurs, appropriate measures should be taken. **QTc Prolongation:** 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 were not included in clinical trials of VIBATIV. Use of VIBATIV should be avoided in patients with these conditions.

ADVERSE REACTIONS: In the 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% (43/938) of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events. Treatment discontinuations due to adverse events occurred in 8% (72/929) of patients treated with VIBATIV, the most common events being nausea and rash (~1% each). Treatment discontinuations due to adverse events occurred in 6% (53/938) of vancomycin-treated patients, the most common events being rash and pruritus (~1% each). The most common adverse events occurring in ≥10% of VIBATIV-treated patients were taste disturbance, nausea, vomiting, and foamy urine. The following table displays the incidence of treatment-emergent adverse drug reactions reported in ≥2% of patients treated with VIBATIV possibly related to the drug.

	VIBATIV (N=929)	Vancomycin (N=938)
Body as a Whole		
Rigors	4%	2%
Digestive System		
Nausea	27%	15%
Vomiting	14%	7%
Diarrhea	7%	8%
Metabolic and Nutritional		
Decreased appetite	3%	2%
Nervous System		
Taste disturbance*	33%	7%
Renal System		
Foamy urine	13%	3%

*Described as a metallic or soapy taste.

In HABP/VABP 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% (60/751) of patients who received VIBATIV, the most common events being acute renal failure and electrocardiogram QTc interval prolonged (~1% each). Treatment discontinuations due to adverse events occurred in 5% (40/752) of vancomycin-patients, the most common events being septic shock and multi-organ failure (<1%). The following table displays the incidence of treatment-emergent adverse drug reactions reported in ≥5% of HABP/VABP patients treated with VIBATIV possibly related to the drug.

	VIBATIV (N=751)	Vancomycin (N=752)
Nausea	5%	4%
Vomiting	5%	4%
Renal Failure Acute	5%	4%

OVERDOSAGE: In the event of overdosage, VIBATIV should be discontinued and supportive care is advised with maintenance of glomerular filtration and careful monitoring of renal function. The clearance of telavancin by continuous venovenous hemofiltration (CVVH) has not been evaluated in a clinical study.

Manufactured for:
Theravance Biopharma Antibiotics, Inc.

Marketed by:
Theravance Biopharma US, Inc.
South San Francisco, CA 94080

Theravance® Biopharma
Medicines That Make a Difference®

VBT 00036-04 June 2016