

Reimbursement Guide Executive Summary



ORBACTIV® (oritavancin) for injection J code is **J2407 injection, oritavancin, 10 mg.**

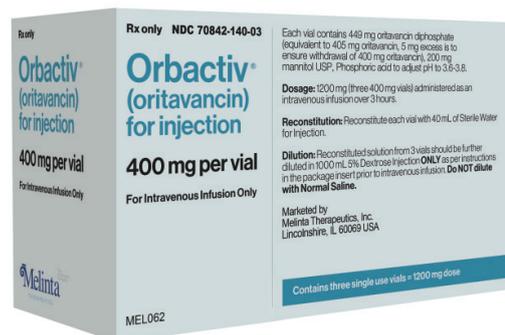
Reimbursement Guide
Executive Summary

Sample Billing Forms

Revised Q1 2022

ORBACTIV® is typically covered and reimbursed by most payers*
when administered in an outpatient setting of care including:

- ED/observation unit
- Hospital outpatient department
- Home infusion
- Free standing infusion center
- Physician office



*Coverage is not guaranteed by Melinta Therapeutics, LLC.
Please consult payers for all coverage, coding & reimbursements.

Please see Indication and Important Safety Information on last page.



Separate Reimbursement for ORBACTIV® (oritavancin)

Setting of Care	Medicare	Medicaid	Private Insurers
Hospital Inpatient	No	Varies; Typically not	Varies; Typically not
Hospital Outpatient	Yes	Varies	Varies
Freestanding Infusion Centers and Physician Offices	Yes	Varies	Varies
Home Health	No, but potential coverage under Part D (see below)	Varies	Varies

Hospital Inpatient	Hospital Outpatient	Freestanding Infusion Centers and Physician Offices	Home Health
Medicare does not reimburse separately for ORBACTIV® when used in the Inpatient setting of care; rather, ORBACTIV® is reimbursed through the MS-DRG payment. Private insurers and State Medicaid agency reimbursement policies vary, but typically will not provide a separate reimbursement for ORBACTIV® in the Inpatient setting.	Medicare will reimburse the hospital for ORBACTIV® separately when used in the outpatient setting of care. Reimbursement will be processed through correct reporting of a drug specific J-Code using the corresponding units delineated in the instructions below. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for ORBACTIV® in the outpatient setting.	Medicare will reimburse for ORBACTIV® separately when used in freestanding infusion centers. Reimbursement will be processed through correct reporting of a drug-specific J-Code using the corresponding units delineated in the instructions below. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for ORBACTIV® in the freestanding infusion center setting.	Medicare does not reimburse separately for ORBACTIV® when used in the Home Health setting of care. However, payment for drug may be available through the patient's Part D plan; drug must be on the formulary and prior authorization may be required. Private insurance and state Medicaid agency reimbursement policies vary; payment for drug may be available under the Pharmacy benefit; drug must be on the formulary and prior authorization may be required.

Quick Coding View for Medicare, Medicaid and Private Insurers

Hospital Inpatient	Freestanding Infusion Centers and Physician Offices
<p>ICD-10-CM Diagnosis Codes: L00.XX-L08.XX, Infections of skin and subcutaneous tissue</p> <p>Additional ICD-10-CM Diagnosis Codes related to cellulitis, abscess, carbuncle, furuncle, and wound infection but outside of the range specified above may also be applicable when using ORBACTIV®. Please call 1-844-ORBACTIV for more information. Please also consult with your payer to obtain specific coverage policies and requirements for covered indications.</p> <p>ICD-10-CM Procedure Codes: 3E03329, Introduction of other anti-infective into peripheral vein, percutaneous approach</p> <p>Common MS-DRGs MS-DRG 602: Cellulitis with MCC MS-DRG 603: Cellulitis without MCC MS-DRG 862: Postoperative and Post-Traumatic infections w/MCC MS-DRG 863: Postoperative and Post-Traumatic infections w/o MCC</p>	<p>ICD-10-CM Diagnosis Codes: Please refer to the Inpatient section for diagnosis codes</p> <p>ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.</p> <p>CPT Procedure Codes: 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour</p> <p>96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour</p>

Hospital Outpatient	Home Health
<p>ICD-10-CM Diagnosis Codes: Please refer to the Inpatient section for diagnosis codes</p> <p>ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.</p> <p>CPT Procedure Codes: May vary by payer 99601: Home infusion/specialty drug administration, per visit (up to 2 hours).</p> <p>99602: Each additional hour (list separately in addition to primary procedure, use CPT code 99602 in conjunction with CPT code 99601)</p> <p>96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour</p> <p>G0463: Hospital outpatient clinic visit for assessment and management of a patient</p>	<p>ICD-10-CM Diagnosis Codes: Please refer to the Inpatient section for diagnosis codes</p> <p>ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.</p> <p>CPT Procedure Codes: May vary by payer 99601: Home infusion/specialty drug administration, per visit (up to 2 hours).</p> <p>99602: Each additional hour (list separately in addition to primary procedure, use CPT code 99602 in conjunction with CPT code 99601)</p> <p>Some private and state Medicaid program payers may use S9494 (Home Infusion Therapy, Antibiotic, Antiviral, Or Antifungal Therapy; Administrative Services, Professional Pharmacy Services, Care Coordination, And All Necessary Supplies And Equipment (Drugs And Nursing Visits Coded Separately), Per Diem)</p>

Healthcare Common Procedure Coding System (HCPCS) Codes

The following are the drug codes for appropriate billing. Medicare, private payers, and state Medicaid programs require UB-04 (CMS-1450) claim forms (for Hospital Outpatient setting) or CMS-1500 (for Freestanding Infusion Center setting) to report the following codes and amount of product used to facilitate appropriate reimbursement.

Setting	HCPCS	Billing Description	Q1 2022 Medicare Payment Rates
Hospital Outpatient	J2407	Injection, oritavancin, 10 mg	ASP + 6% [‡]
Freestanding Infusion Centers and Physician Offices	J2407	Injection, oritavancin, 10 mg	ASP + 6%

[‡] Medicare payment rate is ASP -22.5% for drug purchased through the 340B program.

The following are the billing units for ORBACTIV® (oritavancin).

Setting	HCPCS	Billing Description	Billing Unit
Hospital Outpatient [§]	J2407	Injection, oritavancin, 10 mg	120 units (1200 mg = 120 billing units)
Freestanding Infusion Centers and Physician Offices [§]	J2407	Injection, oritavancin, 10 mg	120 units (1200 mg = 120 billing units)

[§] Please note: Other payers may require different billing units. Please follow payer guidance.

Accurate reporting of the ORBACTIV® HCPCS code, as well as the quantity administered to each patient, is required for appropriate reimbursement. When completing a UB-04/ CMS 1450 or CMS 1500 form for ORBACTIV®, payers may also require the following information:

Drug Name	ORBACTIV® (oritavancin) for injection
Route of Administration	By intravenous infusion over 3 hours
Quantity Administered	1200 mg
Dose of Product	1200 mg
NDC	70842-140-01 Vial 70842-140-03 Carton

Packaging (e.g., single dose vial)
 Three vials packaged in a carton to supply for a single 1200 mg dose treatment

Some payers may also require prescribing information, FDA-approval letter, support of medical necessity and a drug purchase invoice.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MCC=major complication or commodity; MS-DRG=Medicare Severity Diagnosis-Related Group

Please see Indication and Important Safety Information on last page.

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Sample CMS 1450 Billing Form

For service performed in the hospital

This document is provided for informational purposes only.

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

- 0636 for ORBACTIV®
- 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.:

- J2407 is the designated HCPCS code for patients in the hospital outpatient setting.
- 96365 for first hour of IV infusion
- 96366 for each additional hour of IV infusion

Field 46: Report the appropriate unit of service. ORBACTIV® is typically billed in the hospital outpatient setting on a "per 10 mg basis." However, some payers may provide alternate guidance.

Example: A full course of ORBACTIV® is equal to 120 units of J2407 (1200 mg).

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.

The form includes sections for patient name, address, birth date, sex, admission date, and condition codes. It features a table for procedure codes (42-43) and a table for charges (44-49). The charges table shows three entries for ORBACTIV® (J2407) and IV infusion (96365, 96366) with units of 120, 1, and 2 respectively. The form also includes sections for insurance information, patient signature, and provider information.

Field 67: Enter the appropriate diagnosis code; e.g. L00.XX-L08.XX, Infections of skin and subcutaneous tissue.

Note: Other diagnosis codes may apply.

Field 80: Enter the appropriate drug identifying information as required by payer; 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 payer.

Sample CMS 1500 Billing Form

For service performed in physician offices

This document is provided for informational purposes only.

Box 19: Additional Information

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

ORBACTIV® is only sold in cartons containing 3 vials, therefore the carton NDC ending in 03 should be utilized and billed as 1 unit.

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

Box 21: Diagnosis

Enter the appropriate ICD-10-CM diagnosis code; e.g. L00.XX-L08.XX, Infections of skin and subcutaneous tissue. Final code depends on medical record documentation.

Note: Other diagnosis codes may apply.

Box 21: ICD Indicator

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

The form includes sections for patient name, birth date, sex, and insurance information. It features a table for charges (24 D) and a table for units (24 G). The charges table shows three entries for ORBACTIV® (J2407) and IV infusion (96365, 96366) with units of 120, 1, and 2 respectively. The form also includes sections for patient signature, provider information, and insurance details.

Box 24 D: Procedures, services, or suppliers

Enter the appropriate CPT/HCPCS codes and modifiers; e.g.:

- Drug J2407 for ORBACTIV®
- 96365 First hour IV infusion
- 96366 Each additional hour IV infusion

Box 24 G: Units

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

Example: A full course of ORBACTIV® is equal to 120 units of J2407 (1200 mg).

Note: Some payers may provide alternate guidance.

ORBACTIV® (oritavancin) for injection

J code is J2407 injection, oritavancin, 10 mg.

DISCLAIMER

The use of this guide is strictly for informational purposes. The information contained in this document is not intended for purposes of providing clinical practice guidelines for use of ORBACTIV®. Please see the package insert for more information.

Melinta Therapeutics, LLC, specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this sample form. Melinta Therapeutics, LLC, cannot guarantee, nor is responsible for, the payment of any claim. The coding, coverage, and payment for ORBACTIV® may vary by payer, plan, patient, and setting of care. For more information, healthcare professionals should check with individual payers for specific coding, coverage and payment requirements in the use of ORBACTIV®. It is the sole responsibility of the healthcare professional to properly code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient's medical records.

Coding determinations and analyses should always be independently researched and assessed. Providers are responsible for selecting the most appropriate diagnosis code for a specific patient. Providers should contact a patient's health plan, as health plans may have specific code requirements for ORBACTIV® administration.

INDICATION AND USAGE

ORBACTIV® (oritavancin) is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSIs) caused or suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible [MSSA] and -resistant [MRSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus group* (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ORBACTIV® and other antibacterial drugs, ORBACTIV® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications

Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (5 days) after ORBACTIV® administration because the activated partial thromboplastin time (aPTT) test results are expected to remain falsely elevated for approximately 120 hours (5 days) after ORBACTIV® administration.

ORBACTIV® is contraindicated in patients with known hypersensitivity to ORBACTIV®.

Warnings and Precautions

Coagulation test interference: ORBACTIV® has been shown to artificially prolong aPTT for up to 120 hours, and may prolong PT and INR for up to 12 hours, and ACT for up to 24 hours. ORBACTIV® has also been shown to elevate D-dimer concentrations up to 72 hours.

Hypersensitivity reactions, including anaphylaxis, have been reported with the use of antibacterial agents including ORBACTIV®. Discontinue infusion if signs of acute hypersensitivity occur. Monitor closely patients with known hypersensitivity to glycopeptides.

Infusion Related Reactions: Administer ORBACTIV® over 3 hours to minimize infusion-related reactions. Infusion reactions characterized by chest pain, back pain, chills and tremor have been observed with the use of ORBACTIV®, including after the administration of more than one dose of ORBACTIV® during a single course of therapy. Stopping or slowing the infusion may result in cessation of these reactions.

Clostridium difficile-associated diarrhea: Evaluate patients if diarrhea occurs.

Concomitant warfarin use: ORBACTIV® has been shown to artificially prolong PT and INR for up to 12 hours. Patients should be monitored for bleeding if concomitantly receiving ORBACTIV® and warfarin.

Osteomyelitis: Institute appropriate alternate antibacterial therapy in patients with confirmed or suspected osteomyelitis.

Prescribing ORBACTIV® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions (≥3%) in patients treated with ORBACTIV® were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea.

Physician Request Forms



Please see accompanying full Prescribing Information.

