Billing and Coding Guide

Kimyrsa™ (oritavancin) for injection 1,200 mg

KIMYRSA® (oritavancin) for injection
J Code: J2406
Billing Description: Injection, oritavancin (kimyrsa), 10mg

KIMYRSA® can be administered in an outpatient setting of care including:

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

Multiple Settings of Care

Please see Disclaimer on page 8 and Indication and Important Safety Information on page 9.

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Separate Reimbursement for KIMYRSA® (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

Medicare does not reimburse separately for KIMYRSA® when used in the inpatient setting of care; rather, KIMYRSA® 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 KIMYRSA® in the inpatient setting.

Hospital Outpatient

Medicare will reimburse the hospital for KIMYRSA® separately when used in the outpatient setting of care. Medicare reimbursement will be processed through correct reporting of a drug specific J-Code using the corresponding units delineated in this guide. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for KIMYRSA® in the outpatient setting.

Freestanding Infusion Centers and Physician Offices

Medicare will reimburse for KIMYRSA® 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 this guide. Private insurers and State Medicaid agency reimbursement policies vary; many will provide a separate reimbursement for KIMYRSA® in the freestanding infusion center setting.

Home Health

Medicare does not reimburse separately for KIMYRSA® 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.

Please see Disclaimer on page 8 and Indication and Important Safety Information on page 9.

Quick Coding View for Medicare, Medicaid and Private Insurers

Hospital Inpatient

ICD-10-CM Diagnosis Codes: L00.XX-L08.XX, Infections of skin and subcutaneous tissue

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 KIMYRSA®. Please call 1-844-KIMYRSA for more information. Please also consult with your payer to obtain specific coverage policies and requirements for covered indications.

ICD-10-CM Procedure Codes: 3E03329, Introduction of other anti-infective into peripheral vein, percutaneous approach

Potential 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

Hospital Outpatient

ICD-10-CM Diagnosis Codes: Please refer to the inpatient section for diagnosis codes

ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.

CPT Procedure Codes:

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

G0463: Hospital outpatient clinic visit for assessment and management of a patient

Freestanding Infusion Centers and Physician Offices

ICD-10-CM Diagnosis Codes: Please refer to the inpatient section for diagnosis codes

ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.

CPT Procedure Codes:

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

Home Health

ICD-10-CM Diagnosis Codes: Please refer to the inpatient section for diagnosis codes

ICD-10-CM Procedure Codes: do not apply to outpatient procedures. Providers should continue to utilize CPT codes for outpatient procedures.

CPT Procedure Codes:

May vary by payer

99601: Home infusion/specialty drug administration, per visit (up to 2 hours).

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)

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

Healthcare Common Procedure Coding System (HCPCS) Codes

The following are the KIMYRSA® (oritavancin) drug codes and billing units 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	Billing Unit
Hospital Outpatient§	J2406	Injection, oritavancin (kimyrsa), 10mg	120 units (1200 mg = 120 billing units)
Freestanding Infusion Centers and Physician Offices§	J2406	Injection, oritavancin (kimyrsa), 10mg	120 units (1200 mg = 120 billing units)

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

CMS=Centers for Medicare & Medicaid Services.

1. 5 Fed. Reg. 85866, 85869 (Dec. 29, 2020)
2. SSA § 1833(t)(6)(c)(i)

Please see Disclaimer on page 8 and Indication and Important Safety Information on page 9.

Healthcare Common Procedure Coding System (HCPCS) Codes

Accurate reporting of the KIMYRSA® 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 KIMYRSA®, payers may also require the following information:

Drug Name	**KIMYRSA® (oritavancin) for injection**
Route of Administration	By intravenous infusion over 1 hour
Quantity Administered	1200 mg
Dose of Product	1200 mg
NDC 70842-225-01 **NDC 70842-0225-01**	One vial is packaged in a carton to supply a single 1200 mg dose treatment.
Packaging (e.g., single dose vial)	1 vial packed in a single 1200 mg treatment

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

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 KIMYRSA®
- 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.:

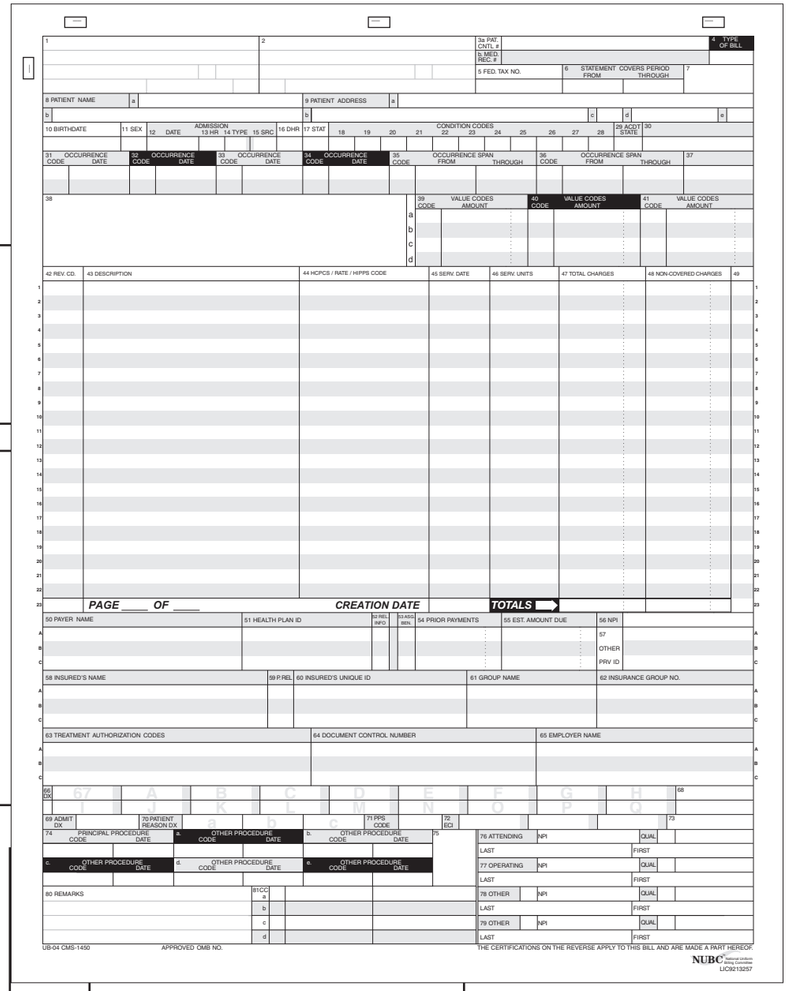
- J2406 is the designated HCPCS code for patients in the hospital outpatient setting.
- 96365 for first hour of IV infusion

Field 46: Report the appropriate unit of service. KIMYRSA® 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 KIMYRSA® is equal to 120 units of J2406 (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.



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.

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

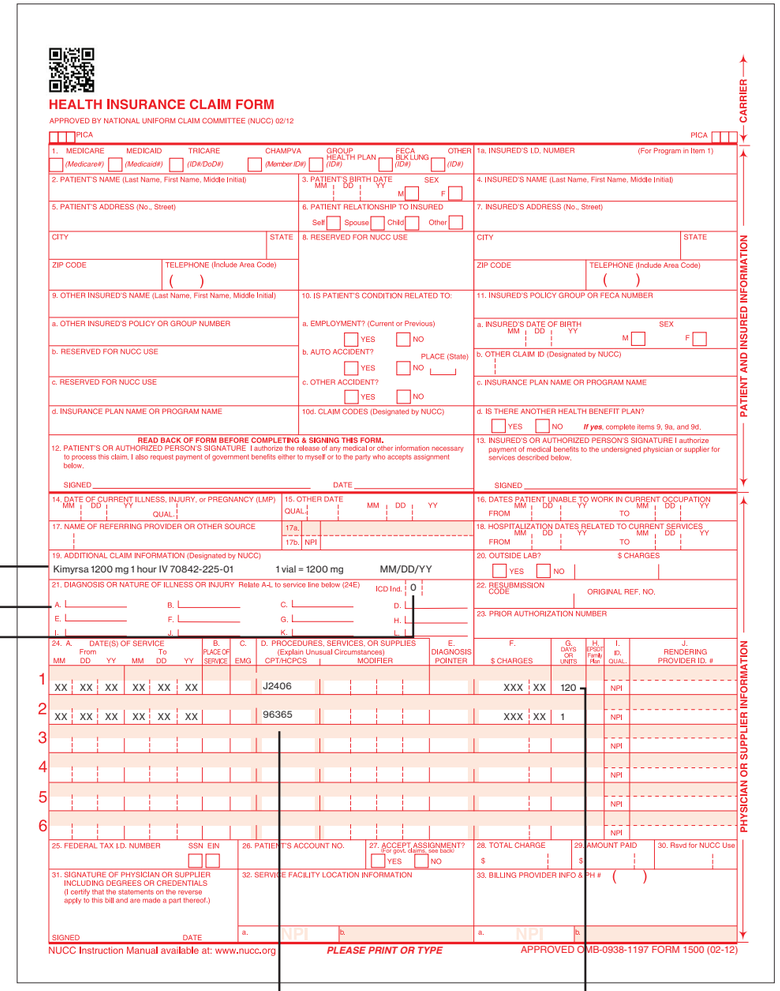
Box 21: Diagnosis

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.



Box 24 D: Procedures, services, or supplies

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

- Drug J2406 for KIMYRSA®
- 96365 First hour IV infusion

Box 24 G: Units

Enter the appropriate number of units of service. KIMYRSA® is billed as 1 unit when using the Misc. J Code J2406.

Example: A full course of KIMYRSA® is equal to 120 units J2406 (1200 mg).

Note: Some payers may provide alternate guidance.

Please see Disclaimer on page 8 and Indication and Important Safety Information on page 9.

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 KIMYRSA®. 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 KIMYRSA® 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 KIMYRSA®. 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 KIMYRSA® administration.

Please see Indication and Important Safety Information on page 9.

KIMYRSA® (oritavancin) for injection

J code is J2406 with Pass-through status

INDICATION AND USAGE

KIMYRSA® (oritavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused or suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible [MSSA] and methicillin-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 KIMYRSA® and other antibacterial drugs, KIMYRSA® 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 KIMYRSA® administration because the activated partial thromboplastin time (aPTT) test results may remain falsely elevated for approximately 120 hours (5 days) after KIMYRSA® administration.

KIMYRSA® is contraindicated in patients with known hypersensitivity to oritavancin products.

Warnings and Precautions

Coagulation test interference: Oritavancin 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. Oritavancin has also been shown to elevate D-dimer concentrations up to 72 hours. For patients who require aPTT monitoring within 120 hours of KIMYRSA® dosing, consider a non-phospholipid dependent coagulation test such as a Factor Xa (chromogenic) assay or an alternative anticoagulant not requiring aPTT.

Serious hypersensitivity reactions, including anaphylaxis, have been reported with the use of oritavancin products including KIMYRSA®. Discontinue infusion if signs of acute hypersensitivity occur. Closely monitor patients with known hypersensitivity to glycopeptides.

Infusion Related Reactions: Infusion reactions characterized by chest pain, back pain, chills and tremor have been observed with the use of oritavancin products (e.g. KIMYRSA®), including after the administration of more than one dose of oritavancin during a single course of therapy. Stopping or slowing the infusion may result in cessation of these reactions.

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

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

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

Prescribing KIMYRSA® in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication 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 oritavancin products were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea. The adverse reactions occurring in ≥2 patients receiving KIMYRSA® were hypersensitivity, pruritus, chills and pyrexia.

The **KIMYRSA® SUPPORT PROGRAM** provides a single point of contact for all your patients' benefits, claims, and reimbursement support needs

- Benefit verification
- Prior authorization support
- Coding and reimbursement information
- Claims appeals process support
- Copay savings program
- Patient assistance program

Scan to download the Patient Support enrollment form

For information about KIMYRSA® support programs, call
1-844-KIMYRSA (1-844-546-9772)
Monday-Friday, 8:00 AM to 8:00 PM, ET.

DISCLAIMER

Content provided for informational purposes only. This information does not guarantee coverage or payment. Codes, coverage, and payment may vary from setting to setting, and from insurer to insurer. The provider submitting a claim is solely responsible for the accuracy of the codes submitted and for compliance with all coverage and reimbursement policies.

Decisions to prescribe KIMYRSA® are by providers working with their patients. The KIMYRSA® Assistance Program provides information about KIMYRSA® and about assistance that may be available to patients who meet certain criteria, including that they are not insured by a federal health care program. More information is available through the KIMYRSA® Assistance Program.

Melinta Therapeutics, LLC, does not guarantee, and assumes no responsibility for the quality, availability, or scope of the KIMYRSA® Assistance Program services. Melinta Therapeutics, LLC, reserves the right to rescind, revoke, or amend this offer at any time without notice. Void where prohibited by law.

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