Reimbursement Guide Executive Summary

Kimyrsa™ (oritavancin) for injection 1,200 mg

KIMYRSA™ (oritavancin) for injection J code is
J3490, Drugs Unclassified Injection
C9399, Unclassified drugs (C-code applied for)

Reimbursement Guide
Executive Summary

Sample Billing Forms
Revised June 2021

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

*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.

melinta therapeutics

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. 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 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 the instructions below. 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.

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

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

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; 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.

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	Q3 2021 Medicare Payment Rates
Hospital Outpatient	C9399	Unclassified drugs or biologics	95% of AWP
Freestanding Infusion Centers and Physician Offices	J3490	Drugs unclassified injection	WAC + 3%

The following are the billing units for KIMYRSA™ (oritavancin).

Setting	HCPCS	Billing Description	Billing Unit
Hospital Outpatient§	C9399	Unclassified drugs or biologics	1 unit (1200 mg = 1 billing unit)
Freestanding Infusion Centers and Physician Offices§	J3490	Drugs unclassified injection	1 unit (1200 mg = 1 billing unit)

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

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** One vial is packaged in a carton to supply a single 1200 mg dose treatment (NDC 70842-225-01).
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.

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.

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.:

- J3490 is the designated HCPCS code for patients in the hospital outpatient setting.
- 96365 for first hour of IV infusion

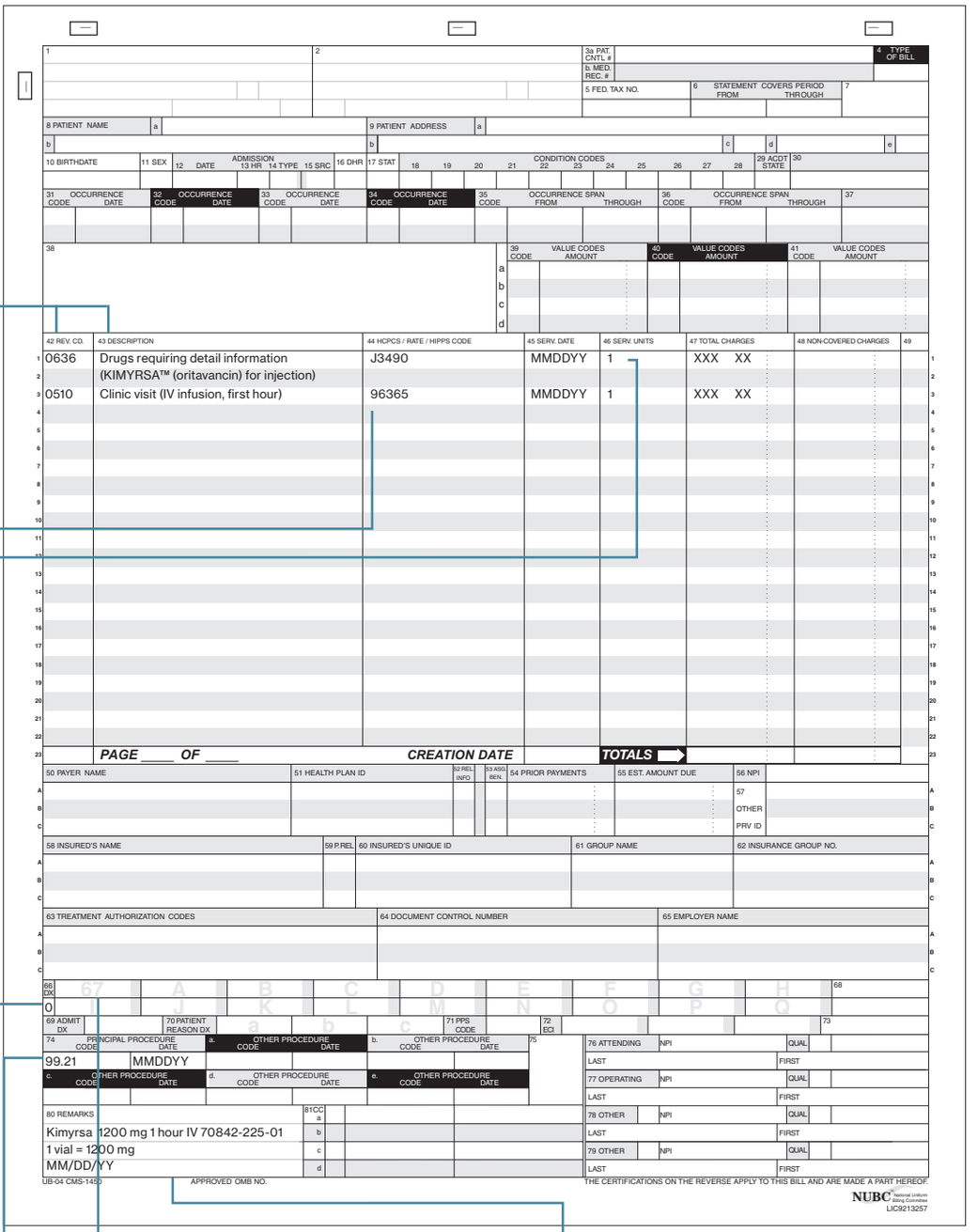
Field 46: Report the appropriate unit of service. KIMYRSA™ is typically billed in the hospital outpatient setting on a "per 1200 mg basis." *However, some payers may provide alternate guidance.*

Example: A full course of KIMYRSA™ is equal to 1 unit of J3490 (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.



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.

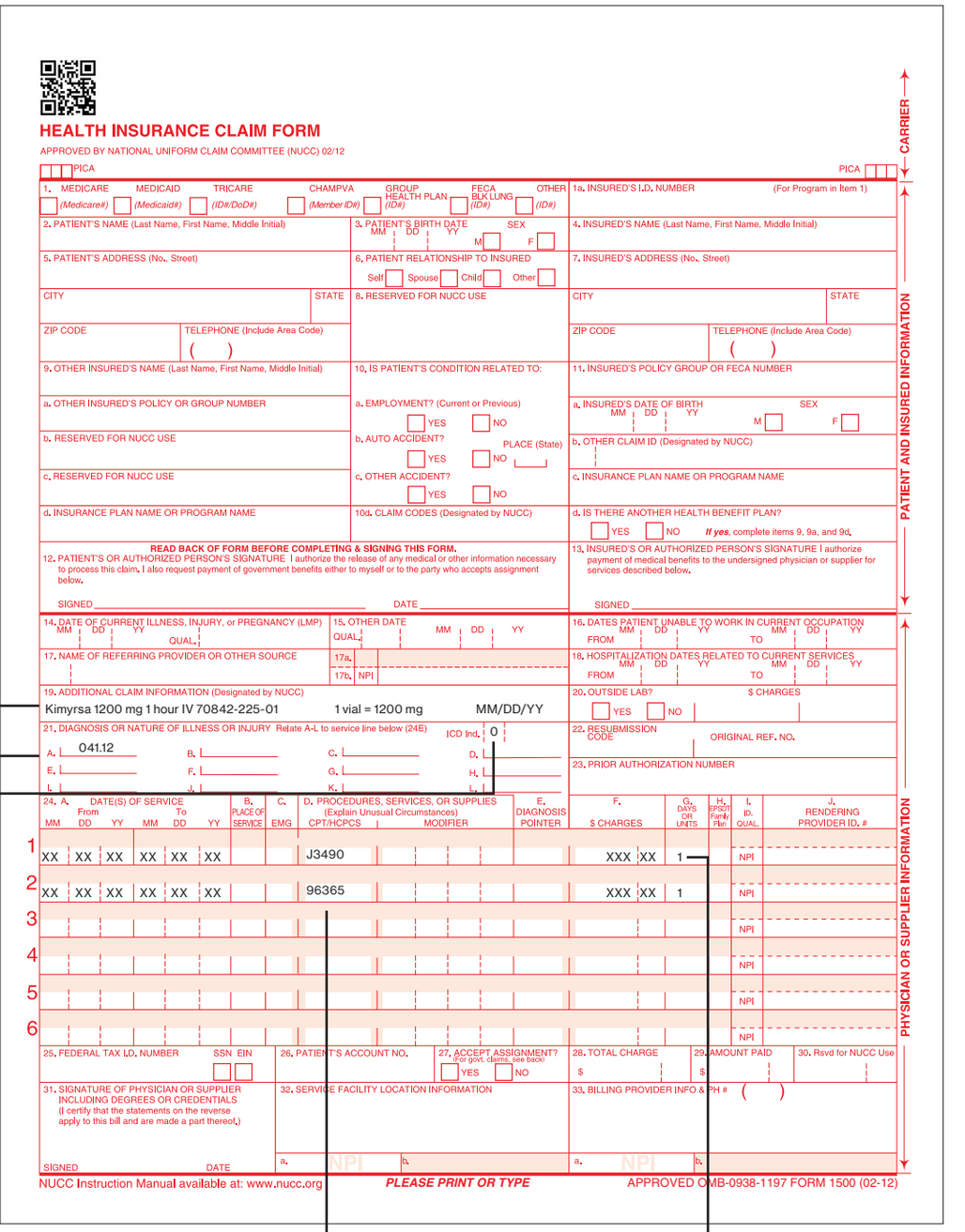
Field 80: Enter the appropriate drug identifying information as required by payer; e.g. brand and generic name, NDC code in 11 digit format, dosage, method of administration, etc.

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

Please see Indication and Important Safety Information on last page.

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? YES NO PLACE (State)

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 MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

Kimyrsa 1200 mg 1 hour IV 70842-225-01 1 vial = 1200 mg MM/DD/YY

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. 041.12 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 XX XX XX	XX XX XX			J3490			XXX.XX	1		NPI	
2 XX XX XX	XX XX XX			96365			XXX.XX	1		NPI	
3										NPI	
4										NPI	
5										NPI	
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 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 suppliers

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

- Drug J3490 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 J3490.

Example: A full course of KIMYRSA™ is equal to 1 unit J3490 (1200 mg).

Note: Some payers may provide alternate guidance.

Please see Indication and Important Safety Information on last page.

KIMYRSA™ (oritavancin) for injection
J code is J3490 drugs unclassified injection

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.

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, pruritis, chills and pyrexia.

Please see accompanying full Prescribing Information.

Physician Request Forms

Kimyrsa™ (oritavancin) for injection 1,200 mg

06/2021

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