1-DOSE, 1-HOUR KIMYRSA® (oritavancin) FOR ABSSSI*: REAL PATIENT RESULTS

89-YEAR-OLD WITH WOUND INFECTION AVOIDED HOSPITALIZATION WITH KIMYRSA

BACKGROUND AND PRESENTATION

REBECCA E.
ABSSSI PATIENT

89-year-old female with history of chronic ulceration to the right anterior tibia presented to physician's office with lower right extremity wound infection

CASE DETAILS

- Patient's infection began following melanoma excision and subsequent radiation on the lower right extremity
- Wound extended to soft tissue structures including anterior tibial tendon; MRI confirmed no bone involvement
- Patient currently resides in assisted-living facility, and her son is also very active in her healthcare

COMORBIDITIES AND HEALTH CONSIDERATIONS

- **Patient presented with the following conditions (all well managed with medication):**
  - Diabetes mellitus
  - Hypertension
  - Hypothyroidism
  - Chronic atrial fibrillation requiring anticoagulation therapy
  - Stage IIIa kidney disease
- **Current medications:**
  - Albuterol
  - Apixaban
  - Atenolol
  - Cetirizine
  - Dulaglutide
  - Ferrous sulfate
  - Furosemide
  - Levothyroxine
  - Nystatin
  - Pravastatin
  - Pregabalin
  - Tramadol
  - Triamcinolone
- **Prior surgeries include:**
  - Total knee replacement
  - Shoulder, cervical spine, and other orthopedic surgeries
  - Melanoma excision from right leg

EVALUATION DETAILS

- BP: 128/77
- HbA1c: 6.2%
- BMI: 35
- WBC: 12.24
- History of cellulitis, incompletely resolved on oral antibiotics
- Infection site culture pathogens: Group B *Streptococcus* and MRSA
- ESR: 66 mm/hr
- ANA: Positive
- Temp: 36.7 °C (97.9 °F)
- Pulse: 77 bpm

DIAGNOSIS

Wound infection positive for Group B *Streptococcus* and MRSA, Eron class II

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 oritavancin and other antibacterial drugs, oritavancin 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 oritavancin administration because the activated partial thromboplastin time (aPTT) test results may remain falsely elevated for approximately 120 hours (5 days) after oritavancin administration. Oritavancin products are contraindicated in patients with known hypersensitivity to oritavancin.

Please see additional Important Safety Information on reverse and accompanying Prescribing Information.

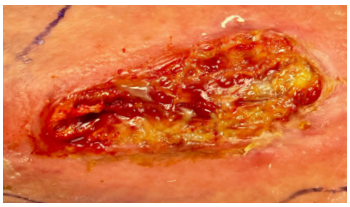
EARLY CLINICAL RESPONSE FOLLOWED BY CURE AT 4 WEEKS WITH KIMYRSA® (oritavancin)

TREATMENT COURSE

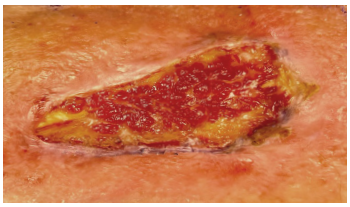
- Multiple rounds of doxycycline and linezolid with poor tolerance and limited efficacy
- Wound debridement with deep cultures following poor response to doxycycline and linezolid
- Patient and her son wished to avoid hospitalization and patient was at risk for worsening renal function with other antibiotics, including vancomycin
- Treated post-operatively with single-dose KIMYRSA, which was well tolerated upon administration at hospital outpatient infusion center
- $0 out-of-pocket cost to the patient with Medicare plus Medigap coverage

KIMYRSA RESULTS

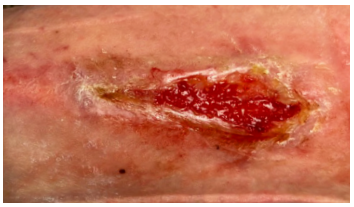
BEFORE
administration of KIMYRSA



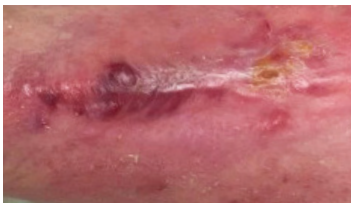
48 HOURS AFTER
administration of KIMYRSA



7 DAYS AFTER
administration of KIMYRSA



4 WEEKS AFTER
administration of KIMYRSA



"Risk of hospital-acquired infection and prolonged immobility would certainly have put this patient at risk in a hospital setting. We were able to avoid the pitfalls of hospitalization and heal a very challenging wound thanks to KIMYRSA, weekly local wound care, and a good son. A great outcome for all those involved!" -Allen Raphael, DPM, FACFAS

"Access to outpatient antibiotic therapy is absolutely ideal for my mother. Her recent hospital stays have resulted in additional infections and illnesses, and set her back physically and mentally. Having the opportunity to receive necessary therapy with KIMYRSA in an outpatient setting greatly reduced the health risks to her, and the strain on our family." -patient's son

This case study is an actual ABSSSI patient who was treated with a single 1200-mg dose of KIMYRSA®. Individual treatment results, insurance coverage, and out-of-pocket costs may vary.
The treating physician is a paid consultant of Melinta Therapeutics, LLC.

IMPORTANT SAFETY INFORMATION (cont)

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 oritavancin 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. 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, 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 oritavancin products and warfarin.

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

Prescribing oritavancin products 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.

Please see additional Important Safety Information on reverse and accompanying Prescribing Information.

melinta therapeutics

Kimyrsa™ (oritavancin) for injection 1,200 mg