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

68-YEAR-OLD WITH CELLULITIS DISCHARGED WITH KIMYRSA

BACKGROUND AND PRESENTATION

RANDOLPH B.
ABSSSI PATIENT

68-year-old male presented to ED with lower right extremity wound marked by erythema, superficial sloughing, and purulent drainage with areas of crusting and scattered eschar

CASE DETAILS

- Patient reports he accidentally scraped his leg on a bucket ~3 weeks prior to presentation
- Topical antibiotic spray failed to alleviate progressive swelling, pain, erythema, and drainage
- Infection progressed despite 2 days of outpatient cephalexin given by PCP
- Admitted to hospital with lower right extremity cellulitis with purulent drainage

COMORBIDITIES AND HEALTH CONSIDERATIONS

- **Patient presented with the following conditions (all well managed with medication):**
  - Congestive heart failure
  - Gout
  - Hypertension
  - Atrial fibrillation for which he relies on a pacemaker and anticoagulation therapy
  - Stage IIIa chronic kidney disease
  - Obesity
- **Current medications:**
  - Cholecalciferol
  - Doxazosin
  - Ferrous sulfate
  - Levothyroxine
  - Metoprolol tartrate
  - Rivaroxaban

EVALUATION DETAILS

- BP: 111/63
- Glucose: 180 mg/dL
- Weight: 115.7 kg (255 lb)
- WBC 11.8 (81%N)
- Infection site culture pathogens: presumed group A *Streptococcus*
- Blood culture pathogens NGTD
- Temp: 36.3 °C (97.4 °F)
- Pulse: 94 bpm
- Cr: 1.55 mg/dL
- eGFR: 48

DIAGNOSIS

Cellulitis caused by presumed group A *Streptococcus*, 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.

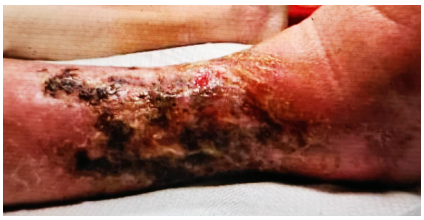
EARLY CLINICAL RESPONSE FOLLOWED BY FULL CURE WITH KIMYRSA® (oritavancin)

TREATMENT COURSE

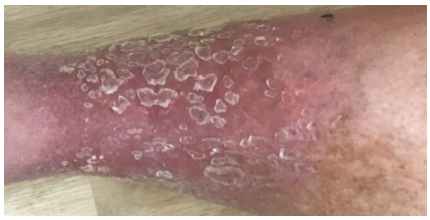
- Initial course of inpatient ampicillin/sulbactam and vancomycin, yielding some improvement in erythema and reduced drainage, but without complete resolution of infection
- Discharged with a prescription for outpatient KIMYRSA, which was well tolerated upon administration in physician's office
- $0 out-of-pocket cost to the patient with Medicare Part B plus Medigap coverage (deductible already met)

KIMYRSA RESULTS

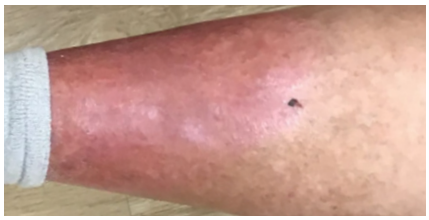
BEFORE
administration of KIMYRSA



3 WEEKS AFTER
administration of KIMYRSA



10 WEEKS AFTER
administration of KIMYRSA



"I wanted to treat Randolph with an IV antibiotic, but I did not want to subject him to a PICC line. I was most comfortable prescribing one dose of KIMYRSA because I knew it would provide efficacy, safety, and convenience—and that is exactly what it did."
-Andrew Dold, DO

"My infection was really horrible. It kept draining so much that I couldn't go to church like I wanted to because my sock and shoe would be soaked. When I went to the hospital, they said they had never seen an infection so bad. I was scheduled to see Dr. Dold when I left the hospital. He gave me KIMYRSA and it really helped a lot. My infection totally cleared up and within a month, it was history. It's a real blessing to be able to get back to doing things I want to do." -Randolph B., patient

This case study is an actual ABSSSI patient who was treated with a single 1200-mg dose of KIMYRSA®. Photo of patient on first page is not the actual patient. 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.

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melinta therapeutics

Kimyrsa™ (oritavancin) for injection 1,200 mg