# Wound Infection Patient Case Study

64-year old female with BMI 34 kg/m$^2$ on warfarin

## Background and presentation

- Patient is a 64-year old obese female, BMI 34 kg/m$^2$.
- She is a diabetic on insulin and also has polyvascular disease.
- She has a history of deep vein thrombosis with an inferior vena cava (IVC) filter, and is on warfarin.
- She presented to ED with an infection at the site of prior bariatric abdominal surgery wound.

## Evaluation

- Lesion: 210 cm$^2$
- BP: 110/68 mmHG
- Temp: 99.7° F
- Blood glucose: 200 mg/dl
- CrCl: 30 mL/min
- WBC: 13,400/mm$^3$

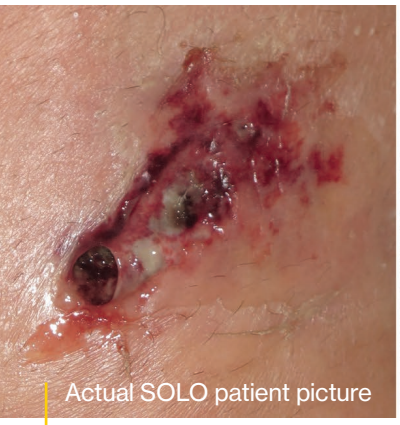
## Diagnosis

- Surgical wound infection
- Presumed gram-positive cocci, presumed MRSA

## Treatment

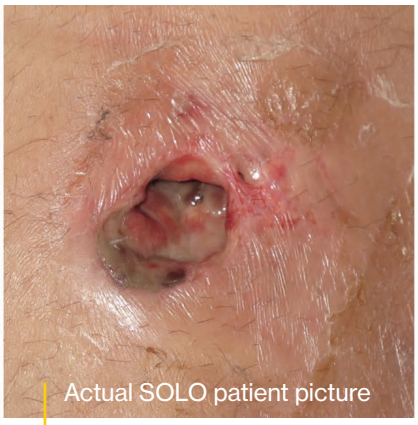
**Single 1200-mg dose of ORBACTIV® (oritavancin)**

## Resolution following administration of single dose ORBACTIV®



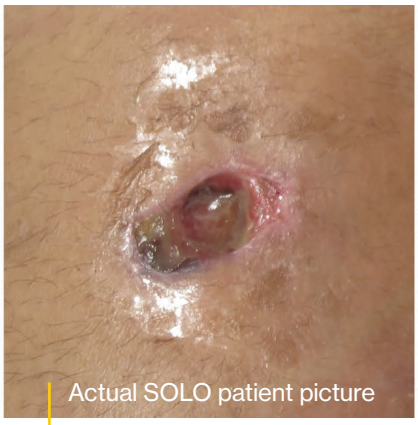
Actual SOLO patient picture

At presentation



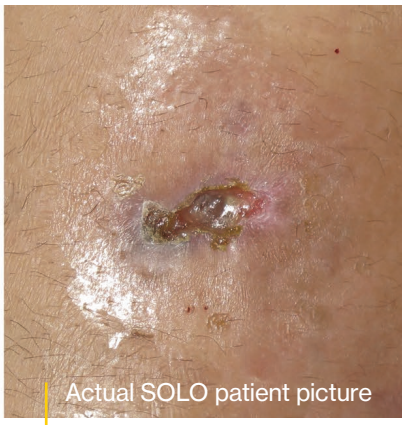
Actual SOLO patient picture

48-72 hours
(clinical response endpoint)*



Actual SOLO patient picture

7-10 days
(clinical evaluation)†



Actual SOLO patient picture

14-24 days
(clinical success endpoint)‡

## Single dose ORBACTIV® is an alternative to multidose vancomycin for the treatment of ABSSSI§

- Effective in treating designated gram-positive pathogens, including MRSA[1,2]
- No dosage adjustment required for mild to moderate renal impairment‖, mild to moderate hepatic impairment¶, age, weight, race, or gender[3]
- No therapeutic monitoring required[3]
- Can be given the outpatient setting of care[4]
- No PICC line required

‖ Mild renal impairment CrCL 50-79mL/min, moderate renal impairment CrCL 30-49mL/min.
¶ Moderate hepatic impairment (Child-Pugh Class B).

**These hypothetical case studies are meant to be illustrative. They are not intended to offer medical advice.Determination of appropriate treatment is at the discretion of the physician. Treatment results may vary by patient.**

**For more ORBACTIV® patient stories, visit orbactiv.com/patient-stories**

### § INDICATION AND USAGE

ORBACTIV® (oritavancin) for injection 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®.

**Please see reverse for additional Important Safety Information.**

Orbactiv™ (oritavancin) for injection 1200 mg

*Efficacy and Efficiency in One Dose*

## Clinical response rates with the largest MRSA subset in a single-dose ABSSSI program[1-3]

### Pooled response rates for SOLO I and SOLO II clinical trials*

| Endpoints | ORB‖ (n=978) | VAN‖ (n=981) | MRSA: ORB¶ (n=204) | MRSA: VAN¶ (n=201) |
|---|---|---|---|---|
| Early clinical response (primary endpoint)† | 81.2% (794) | 80.9% (794) | 81.4% (166) | 80.6% (162) |
| ≥20% reduction in lesion size (secondary endpoint)‡ | 86.4% (845) | 84.1% (825) | 93.1% (190) | 87.1% (175) |
| Clinical success (secondary endpoint)§ | 81.2% (794) | 80.2% (787) | 83.3% (170) | 84.1% (169) |

*Pooled data calculated based on SOLO I and SOLO II data in Prescribing Information. SOLO I and SOLO II were two identical, randomized, double-blind, non-inferiority, Phase 3 trials comparing ORBACTIV® 1200 mg to vancomycin 1 g or 15 mg/kg BID for 7-10 days.
†Early clinical response: composite of the cessation of spread or reduction in size of baseline lesion, absence of fever, and no rescue antibacterial drug at 48-72 hours.
‡Patients achieving a 20% or greater reduction in lesion area from baseline at 48-72 hours after initiation of therapy.
§Clinical success: complete or nearly complete resolution of baseline signs and symptoms at post-therapy evaluation at days 14-24.
‖Modified intent-to-treat population.
¶Microbiological intent-to-treat population of the SOLO pool.

## ORBACTIV® is covered and reimbursed by most health plans[5]**

For information about coding and financial assistance for patients, please contact:

**1-844-ORBACTIV (1-844-672-2284)**
Monday - Friday, 8:00 AM - 8:00 PM ET

**orbactivassistanceprogram@melinta.com**

**Melinta Therapeutics, LLC, does not guarantee that coverage or payment will occur for any particular claim. Please consult payers for all coverage, coding and reimbursement.

### IMPORTANT SAFETY INFORMATION (continued)

### 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.

**Please see reverse for complete Indication and additional Important Safety Information. Please see accompanying Full Prescribing Information.**

**References: 1.** Corey GR, et al. *Clin Infect Dis.* 2015;60:254-262. **2.** Corey GR, et al. *N Engl J Med*. 2014;370:2180-90. **3.** ORBACTIV® [package insert]: Melinta Therapeutics, LLC; 2019. **4.** Lodise TP et al, *Open Forum Infect Dis* 2017;4(1):ofw274. **5.** Data on file, Melinta Therapeutics, LLC.



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