



NHS MEDICAL POLICY

Long Acting Lipoglycopeptide Antimicrobial Agents Medicine 2019-002

FDA approved alternative long-acting agents for the treatment of skin and soft tissue infections include Dalvance (dalbavancin), Orbactiv (oritavancin) and Vibativ (telavancin). One of these antibiotics may be indicated for use when ALL the following are present:

1	For Orbactiv (oritavancin) and Vibativ (telavancin): The member is an adult age 18 or over. For Dalvance (dalbavancin) only: The member is a child, 3 months of age or more, or an adult.
2	The member has an acute bacterial skin or skin structure infection requiring antibiotic therapy. For Vibativ (telavancin) only: This antibiotic may also be used for hospital-acquired or ventilator-associated pneumonia.
3	The member does NOT have osteomyelitis.
4	The bacterial pathogen is culture proven or strongly suspected to be gram-positive. Examples include methicillin-susceptible and methicillin-resistant Staphylococcus aureus, Streptococci or vancomycin-susceptible Enterococcus faecalis.
5	The provider has documented a clinical reason why the member cannot take an oral antibiotic. OR, the provider has documented why the member is not an appropriate clinical candidate for an oral antibiotic.
6	The member requires at least 7 days of parenteral antibiotic therapy.
7	The provider has documented a clinical reason why the member cannot take vancomycin, linezolid or another appropriate antibiotic. OR, the provider has documented why the member is not an appropriate clinical candidate for vancomycin, linezolid or another appropriate antibiotic.
8	For Orbactiv (oritavancin) only: The member does not take anticoagulant medication and does not require coagulation tests for at least 5 days following the planned administration of oritavancin. (Note: This antibiotic can prolong coagulation tests, such as PT, PTT or ACT.)
9	For Vibativ (telavancin) and Dalvance (dalbavancin): Dosing has been appropriately adjusted for any renal function impairment, if present.

SOURCES

1. Arhin FF, et al, In vitro stepwise selection of reduced susceptibility to lipoglycopeptides in enterococci. *Diagn Microbiol Infect Dis*. 2017;89(2):168.
2. Belley A, et al, Comparative Pharmacodynamics of Single-Dose Oritavancin and Daily High-Dose Daptomycin Regimens against Vancomycin-Resistant *Enterococcus faecium* Isolates in an In Vitro Pharmacokinetic/Pharmacodynamic Model of Infection. *Antimicrob Agents Chemother*. 2017;61(10).
3. Corey GR, et al, SOLO II Investigators. 2015. Single-dose oritavancin versus 7–10 days of vancomycin in the treatment of gram-positive acute bacterial skin and skin structure infections: the SOLO II noninferiority study. *Clin Infect Dis* 60:254–262.
4. Jones RN, et al, Use of in vitro vancomycin testing results to predict susceptibility to oritavancin, a new long-acting lipoglycopeptide. *Antimicrob Agents Chemother*. 2015 Apr;59(4):2405-9.
5. Mendes RE, et al, Oritavancin activity against vancomycin-susceptible and vancomycin-resistant *Enterococci* with molecularly characterized glycopeptide resistance genes recovered from bacteremic patients, 2009-2010. *Antimicrob Agents Chemother*. 2012 Mar;56(3):1639-42.
6. Rubino CM et al, Population pharmacokinetic analysis for a single 1,200-milligram dose of oritavancin using data from two pivotal phase 3 clinical trials. *Antimicrob Agents Chemother*. 2015;59(6):3365.
7. Stewart CL, et al, Real-World Experience with Oritavancin Therapy in Invasive Gram-Positive Infections. *Infect Dis Ther*. 2017;6(2):277.
8. [Accessdata.fda.gov](https://www.accessdata.fda.gov) was accessed Jul 31, 2018 and package insert – prescribing information.
9. Rappo U, et al. Dalbavancin for the Treatment of Osteomyelitis in Adult Patients: A Randomized Clinical Trial of Efficacy and Safety. *Open Forum Infect Dis*. 2018 Dec 10;6(1):ofy331.
10. Almangour TA, et al. Dalbavancin for the management of gram-positive osteomyelitis: Effectiveness and potential utility. *Diagn Microbiol Infect Dis*. 2019 Mar;93(3):213-218.
11. UpToDate.com was accessed Jul 31, 2018, Jul 29, 2019 & May 14, 2020:
 - Dalbavancin: Drug information, Lexicomp
 - Oritavancin: Drug information, Lexicomp
 - Telavancin: Drug information, Lexicomp
 - Methicillin-resistant *Staphylococcus aureus* (MRSA) in adults: Treatment of skin and soft tissue infections
 - Pharmacology of antimicrobial agents for treatment of methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococcus.
12. Personal communication with Vinay Bhargava, PharmD, MBA, Chief Pharmacy Officer, Hospitality Rx, on Jul 31, 2018.

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

J0875, J2407, J3095

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
06/11/2020	This was altered to include additional references reviewed, but no material changes.
06/11/2021	Annual review and approval by UM Committee
06/10/2022	Annual review and approval by UM Committee
05/26/2023	Annual review and approval by UM/QM Committee
05/20/2024	Annual review and approval by UM/QM Committee

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PROPRIETARY POLICY