| WellMed<br>Doctors helping patients for more than 25 years | **Effective Date:** 05/24/2023 | **Revision Date(s):**<br>02/13/20, 05/18/21, 06/10/21<br>03/08/23 |
|---|---|---|
| **Department: PHARMACY** | **MMC Review/ Approval Date(s):**<br>1/15/19, 6/23/20, 08/10/21,<br>05/23/2023 | **Page(s): 19** |

**Policy Number: 002.004**

**Title: Coverage Determination Policy for Antimicrobials:**

- **Dalbavancin (Dalvance), Daptomycin (Cubicin), Oritavancin (Orbactiv, Kimyrsa)**

**Regions:** ☒ **Texas** ☐ **Florida** ☐ **Indiana** ☐ **New Jersey** ☒ **New Mexico**

**Impacted Areas:**

| | |
|---|---|
| ☒ Network Management/Provider Services | ☒ Utilization Management |
| ☐ Member services | ☐ Case management |
| ☐ Quality Management | ☐ Disease management |
| ☐ Credentialing | ☒ Claims |
| ☐ IT | ☐ Human resources |
| ☐ Administration | ☐ Finance |
| ☐ Compliance/delegation | ☒ Pharmacy |
| | ☐ ALL |

| | | |
|---|---|---|
| **Approved by:**<br>Vincent Huerta, MD, CHCQM<br>Senior Medical Director | Vincent F Huerta Jr, MD, CHCQM<br>Digitally signed by Vincent F Huerta Jr, MD, CHCQM<br>Date: 2023.05.24 14:44:44 -05'00' | **Date:** 05/24/2023 |
| **Reviewed by:**<br>Pathik Tripathi, Pharm.D, MS<br>Director, Clinical Pharmacy | Pathik Tripathi<br>Digitally signed by Pathik Tripathi<br>Date: 2023.05.24 10:00:09 -05'00' | **Date:** 05/24/2023 |

**Available LCD/NCD/LCA: None**

**Disclaimer:**

WellMed Coverage Determination Policies are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support WellMed coverage decision making. WellMed may modify these Policy Guidelines at any time. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the WellMed Coverage Determination Policies is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.


**Title: Coverage Determination Policy for Antimicrobials:**

- **Dalbavancin (Dalvance), Daptomycin (Cubicin), Oritavancin (Orbactiv, Kimyrsa)**

**Table of Contents** **Page**



**Coverage Policy Number:** 002.004

**Line of Business:** Medicare Part B

**Policy Type:** Prior Authorization

## Coverage Determination:

## Initial/New Requests

1. WellMed Medical Management will cover **Dalbavancin (Dalvance)** as medically necessary when **ALL** of the following are met:

   A. Patient has diagnosis of acute bacterial skin and skin structure infections (ABSSSI)

   B. Infection is caused by one of the following designated susceptible strains of Gram-positive microorganisms as evidenced by culture and susceptibility results: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes, Streptococcus agalactiae*, *Streptococcus dysgalactiae, Streptococcus anginosus* group (including *S. anginosus, S. intermedius, S. constellatus*) and *Enterococcus faecalis* (vancomycin susceptible strains).

   C. Dose is consistent with FDA approved dosing and appropriately adjusted for patient's condition (renal dosing as indicated)

**NOTE**: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dalvance and other antibacterial drugs, Dalvance should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

2. WellMed Medical Management will cover **Daptomycin (Cubicin)** as medically necessary for **complicated skin and skin structure infections (cSSSI)** in adult patients when **ALL** of the following criteria are met:

   A. Infection is caused by susceptible isolates of the following Gram-positive bacteria as evidenced by culture and susceptibility results: *Staphylococcus aureus* (including methicillin-resistant isolates*), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

   B. Dose is consistent with FDA approved dosing and appropriately adjusted for patient's condition (renal dosing as indicated)

3. WellMed Medical Management will cover **Daptomycin (Cubicin)** as medically necessary for **Bloodstream Infections (Bacteremia) in Adult Patients (including right-sided infective endocarditis)** when **ALL** of the following criteria are met:
   A. Infection is caused by caused by Methicillin-Susceptible and Methicillin- Resistant *Staphylococcus aureus* isolates as evidenced by culture and susceptibility results

   B. Dose is consistent with FDA approved dosing and appropriately adjusted for patient's condition (renal dosing as indicated)

***** Additional indications (below) found in guidelines may be approved on a case-by-case basis*****

***Bacteremia associated with intravascular line*** (MRSA, Methicillin-resistant, coagulase-negative staphylococci; ampicillin-resistant, vancomycin-susceptible Enterococcus faecalis/faecium; or ampicillin- and vancomycin-resistant Enterococcus faecalis/faecium)

- Antibiotic therapy is recommended for 7 to 14 days
- Daptomycin 6 to 8 mg/kg IV once daily

***Osteomyelitis*** (MRSA and coagulase-negative staphylococci)

- Antibiotic therapy for at least 8 weeks is recommended
- Daptomycin 6 mg/kg/day IV once daily

***Septic Arthritis*** (MRSA)

- Antibiotic therapy is recommended for 3 to 4 weeks
- Daptomycin 6 mg/kg/day IV once daily

***Febrile Neutropenia*** (MRSA or VRE)

- Antibiotic therapy is recommended for 3 to 4 weeks
- Daptomycin 6 mg/kg/day IV once daily

***Prosthetic Joint Infections*** (MRSA, MSSA, penicillin resistant and susceptible enterococci)

- Antibiotic therapy for at least 6 weeks is recommended for adult patients
- Daptomycin 6 mg/kg/day IV once daily

**NOTE:** To reduce the development of drug-resistant bacteria and maintain the effectiveness of daptomycin and other antibacterial drugs, only use daptomycin to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**Limitations of use:** Daptomycin is not indicated for the treatment of pneumonia or for the treatment of left-sided endocarditis due to Staphylococcus aureus.

4. WellMed Medical Management will cover **Oritavancin (Orbactiv, Kimyrsa)** as medically necessary when **ALL** of the following are met:

   A. Patient has Acute bacterial skin and skin structure infections (ABSSSI)

   B. Infection is caused by one of the following designated susceptible strains of Gram-positive microorganisms as evidenced by culture and susceptibility results: Staphylococcus aureus (including methicillin-susceptible and methicillin–resistant 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).

   C. Patient is not concurrently receiving unfractionated heparin.

   D. Dose is consistent with FDA approved dosing

**NOTE:** 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 infections that are proven or strongly suspected to be caused by susceptible bacteria.

## Renewal/Continuation of Therapy Requests

- WellMed Medical Management will cover **Dalbavancin (Dalvance)** as medically necessary for continuation of therapy upon hospital discharge *{weekly split dosing (1,000 mg followed by 500 mg one week later}* if patients meets initial coverage criteria for diagnosis.

- WellMed Medical Management will cover **Daptomycin (Cubicin)** as medically necessary for continuation of therapy upon hospital discharge if patients meets initial coverage criteria for diagnosis. Total duration of therapy should follow usual dosing guidelines.

## FDA Approved Dose and Indication

| Description | Indication | Approved Dosing |
|---|---|---|
| **Dalbavancin (Dalvance)** | Acute bacterial skin and skin structure infections (ABSSSI) | *NORMAL renal function (CrCl ≥ 30mL/min or on regular hemodialysis):*<br>Total dose of 1500 mg, administered either as a single dose, or 1000 mg followed one week later by 500 mg |
| | | *For renal impairment (CrCl <30 ml/min) and who are NOT receiving regularly scheduled hemodialysis*:<br>Total dose of 1125 mg, administered as a single dose, or 750 mg followed one week later by 375 mg |
| **Daptomycin (Cubicin)** | Complicated skin and skin structure infections (cSSSI) in adult | *NORMAL renal function (CrCl ≥ 30mL/min):*<br>4 mg/kg IV once every 24 hours for 7 to 14 days. |
| | | *For renal impairment (CrCl<* 30 mL/min) **including adult patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD):**<br>4 mg/kg once every 48 hours for 7 to 14 days |
| | Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis caused by methicillin-susceptible and methicillin-resistant isolates | *NORMAL renal function (CrCl ≥ 30mL/min):*<br>6 mg/kg IV once every 24 hours for 2 to 6 weeks<br>(Maximum dosage: Higher doses of 8 to 10 mg/kg IV every 24 hours may be used)<br>*For renal impairment (CrCl<* 30 mL/min) **including adult patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD):** 6 mg/kg IV once every 48 hours for 2 to 6 weeks<br>**NOTE:** There are limited safety data for the use of CUBICIN for more than 28 days of therapy. In the Phase 3 trial, there were a total of 14 adult patients who were treated with CUBICIN for more than 28 days. |
| **Oritavancin**<br>**(Kimyrsa, Orbactiv)** | Acute bacterial skin and skin structure infections | 1200 mg single dose IV infusion over 1 hour **(Kimyrsa)**<br>1200 mg single dose IV infusion over 3 hours **(Orbactiv)** |

## General Background

Dalvance is a semisynthetic lipoglycopeptide antibacterial agent that inhibits cell wall peptidoglycan cross-linking by binding to the terminal of the D-alanyl-D-alaine pentapeptide chain in nascent peptidoglycan. Even though the mechanism of action is similar between dalbavancin and vancomycin, some vancomycin-resistant enterococci and staphylococci with intermediate sensitivity to glycopeptides remain sensitive to dalbavancin.

Cubicin is a lipopeptide antibacterial indicated for the treatment of adult and pediatric patients (1 to 17 years of age) with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only).

Orbactiv and Kimyrsa are lipoglycopeptide antibacterial drugs indicated for the treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms. Orbactiv and Kimyrsa have been shown to artificially prolong aPTT for up to 120 hours, PT and INR for up to 12 hours, and activated clotting time (ACT) for up to 24 hours following administration of a single 1200 mg dose by binding to and preventing action of the phospholipid reagents commonly used in laboratory coagulation tests. Orbactiv and Kimyrsa have also been shown to elevate D-dimer concentrations up to 72 hours after administration.

Medicare does not have a National Coverage Determination (NCD) for Dalbavancin (Dalvance), Daptomycin (Cubicin), or Oritavancin (Orbactiv, Kimyrsa). There are no Local Coverage Determinations (LCD) or Local Coverage Articles (LCA) that address Dalbavancin (Dalvance), Daptomycin (Cubicin), or Oritavancin (Orbactiv, Kimyrsa) for Texas at the time of this policy creation.

## Clinical Evidence

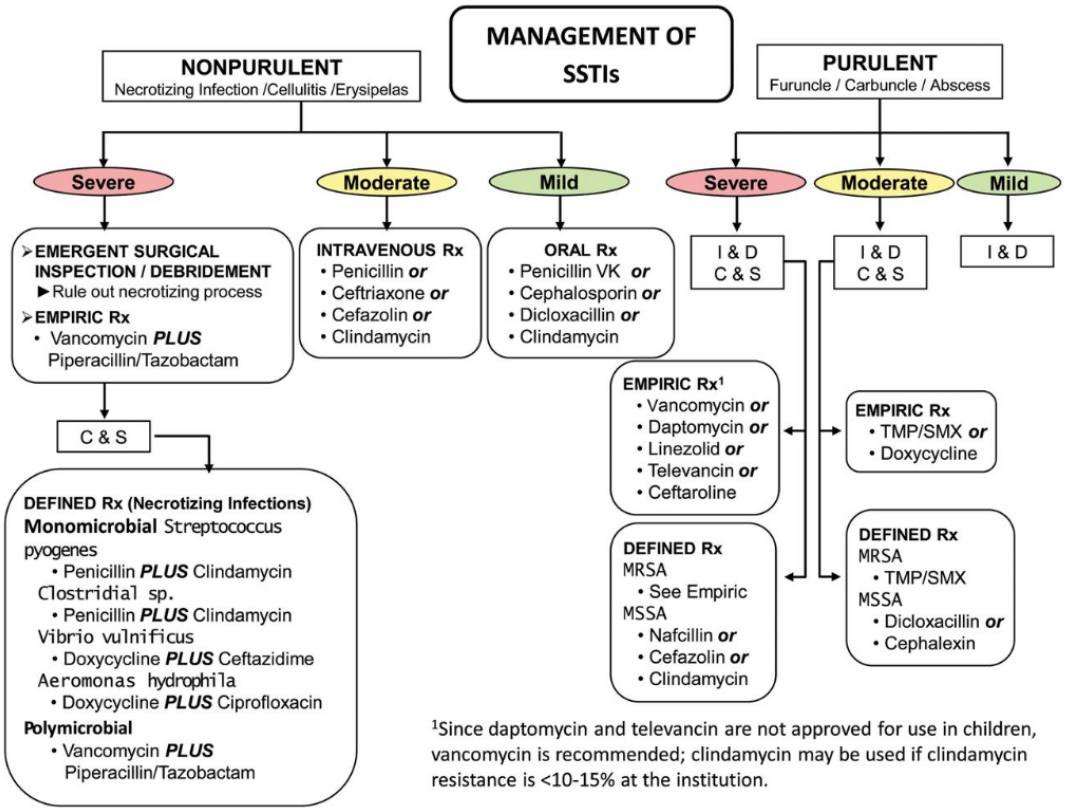
**Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America:**

This practice guideline provides recommendations for the diagnosis and management of skin and soft tissue infections (SSTIs) in otherwise healthy hosts and compromised hosts of all age groups. These recommendations take on new importance because of a dramatic increase in the frequency and severity of infections and the emergence of resistance to many of the antimicrobial agents commonly used to treat SSTIs in the past. For example, there was a 29% increase in the total hospital admissions for these infections between 2000 and 2004 [5]. In addition, 6.3 million physician's office visits per year are attributable to SSTIs [6]. Similarly, between 1993 and 2005, annual emergency department visits for SSTIs increased from 1.2 million to 3.4 million patients [7]. Some of this increased frequency is related to the emergence of community-associated methicillin-resistant Staphylococcus aureus (MRSA) [5].

These infections have diverse etiologies that depend, in part, on different epidemiological settings. As a result, obtaining a careful history that includes information about the patient's immune status, geographic locale, travel history, recent trauma or surgery, previous antimicrobial therapy, lifestyle, hobbies, and animal exposure or bites is essential when developing an adequate differential diagnosis and an appropriate index of suspicion for specific etiological agents. Recognition of the physical examination findings and understanding the anatomical relationships of skin and soft tissue are crucial for establishing the correct diagnosis. In some cases, this information is insufficient and biopsy or aspiration of tissue may be necessary. In addition, radiographic procedures may be critical in a small subset of patients to determine the level of infection and the presence of gas, abscess, or a necrotizing process. Last, surgical exploration or debridement is an important diagnostic, as well as therapeutic, procedure in patients with necrotizing infections or myonecrosis and may be important for selected immunocompromised hosts.

**Purulent skin and soft tissue infections (SSTIs).** Mild infection: for purulent SSTI, incision and drainage is indicated. Moderate infection: patients with purulent infection with systemic signs of infection. Severe infection: patients who have failed incision and drainage plus oral antibiotics or those with systemic signs of infection such as temperature >38°C, tachycardia (heart rate >90 beats per minute), tachypnea (respiratory rate >24 breaths per minute) or abnormal white blood cell count (<12 000 or <400 cells/µL), or immunocompromised patients.

**Nonpurulent SSTIs.** Mild infection: typical cellulitis/erysipelas with no focus of purulence. Moderate infection: typical cellulitis/erysipelas with systemic signs of infection. Severe infection: patients who have failed oral antibiotic treatment or those with systemic signs of infection (as defined above under purulent infection), or those who are immunocompromised, or those with clinical signs of deeper infection such as bullae, skin sloughing, hypotension, or evidence of organ dysfunction. Two newer agents, tedizolid and dalbavancin, are also effective agents in SSTIs, including those caused by methicillin-resistant *Staphylococcus aureus*, and may be approved for this indication by June 2014. Abbreviations: C & S, culture and sensitivity; I & D, incision and drainage; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-susceptible *Staphylococcus aureus*; Rx, treatment; TMP/SMX, trimethoprim-sulfamethoxazole.




[1]Since daptomycin and televancin are not approved for use in children, vancomycin is recommended; clindamycin may be used if clindamycin resistance is <10-15% at the institution.

**CLINICAL STUDIES: Dalvance**

Acute Bacterial Skin and Skin Structure Infections:

DALVANCE Two-dose Regimen (1000 mg Day 1; 500 mg Day 8)

Adult patients with ABSSSI were enrolled in two Phase 3, randomized, double-blind, double-dummy clinical trials of similar design (Trial 1 and Trial 2). The Intent-to-Treat (ITT) population included 1,312 randomized patients. Patients were treated for two weeks with either a two-dose regimen of intravenous DALVANCE (1000 mg followed one week later by 500 mg) or intravenous vancomycin (1000 mg or 15 mg/kg every 12 hours, with the option to switch to oral linezolid after 3 days). DALVANCE-treated patients with creatinine clearance of less than 30 mL/min received 750 mg followed one week later by 375 mg. Approximately 5% of patients also received a protocol-specified empiric course of treatment with intravenous aztreonam for coverage of Gram-negative pathogens.

The specific infections in these trials included cellulitis (approximately 50% of patients across treatment groups), major abscess (approximately 30%), and wound infection (approximately 20%). The median lesion area at baseline was 341 cm2. In addition to local signs and symptoms of infection, patients were also required to have at least one systemic sign of disease at baseline, defined as temperature 38°C or higher (approximately 85% of patients), white blood cell count greater than 12,000 cells/mm3 (approximately 40%), or 10% or more band forms on white blood cell differential (approximately 23%). Across both trials, 59% of patients were from Eastern Europe and 36% of patients were from North America. Approximately 89% of patients were Caucasian and 58% were males. The mean age was 50 years and the mean body mass index was 29.1 kg/m2.

The primary endpoint of these two ABSSSI trials was the clinical response rate where responders were defined as patients who had no increase from baseline in lesion area 48 to 72 hours after initiation of therapy, and had a temperature consistently at or below 37.6° C upon repeated measurement. Table 7 summarizes overall clinical response rates in these two ABSSSI trials using the pre-specified primary efficacy endpoint in the ITT population

Another secondary endpoint in these two ABSSSI trials was the clinical success rate assessed at a follow-up visit occurring between Days 26 to 30. Clinical Success at this visit was defined as having a decrease in lesion size (both length and width measurements), a temperature of 37.6° C or lower, and meeting pre-specified criteria for local signs: purulent discharge and drainage absent or mild and improved from baseline, heat/warmth & fluctuance absent, swelling/induration & tenderness to palpation absent or mild.

DALVANCE 1500 mg Single Dose Regimen

Adult patients with ABSSSI were enrolled in a Phase 3, double-blind, clinical trial. The ITT population included 698 patients who were randomized to DALVANCE treatment with either a single 1500 mg dose or a two-dose regimen of 1000 mg followed one week later by 500 mg (Trial 3). Patients with creatinine clearance less than 30 mL/min had their dose adjusted (Section 2.2). Approximately 5% of patients also received a protocol-specified empiric course of treatment with intravenous aztreonam for coverage of Gram-negative pathogens. The specific infections and other patient characteristics in this trial were similar to those described above for previous ABSSSI trials.

The primary endpoint in this ABSSSI trial was the clinical response rate where responders were defined as patients who had at least a 20% decrease from baseline in lesion area 48 to 72 hours after randomization without receiving any rescue antibacterial therapy. The secondary endpoint was the clinical success rate at a follow-up visit occurring between Days 26 and 30, with clinical success defined as having at least a 90% decrease from baseline in lesion size, a temperature of 37.6° C or lower, and meeting pre-specified criteria for local signs: purulent discharge and drainage absent or mild and improved from baseline (for patients with wound infections), heat/warmth and fluctuance absent, swelling/induration and tenderness to palpation absent or mild. Table 11 summarizes results for these two endpoints in the ITT population. Note that there are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at the follow-up visit. Therefore, comparisons between treatment groups based on clinical success rates at this visit cannot be utilized to establish non-inferiority

**CLINICAL STUDIES: Cubicin**

Complicated Skin and Skin Structure Infections Adults with cSSSI

Adult patients with clinically documented complicated skin and skin structure infections (cSSSI) were enrolled in two randomized, multinational, multicenter, investigator-blinded trials comparing CUBICIN (4 mg/kg IV every 24h) with either vancomycin (1 g IV q12h) or an anti-staphylococcal semisynthetic penicillin (i.e., nafcillin, oxacillin, cloxacillin, or flucloxacillin; 4 to 12 g IV per day). Patients could switch to oral therapy after a minimum of 4 days of IV treatment if clinical improvement was demonstrated. Patients known to have bacteremia at baseline were excluded. Patients with creatinine clearance (CLCR) between 30 and 70 mL/min were to receive a lower dose of CUBICIN as specified in the protocol; however, the majority of patients in this subpopulation did not have the dose of CUBICIN adjusted.

One trial was conducted primarily in the United States and South Africa (study 9801), and the second was conducted at non-US sites only (study 9901). The two trials were similar in design but differed in patient characteristics, including history of diabetes and peripheral vascular disease. There were a total of 534 adult patients treated with CUBICIN and 558 treated with comparator in the two trials. The majority (89.7%) of patients received IV medication exclusively.

The efficacy endpoints in both trials were the clinical success rates in the intent-to-treat (ITT) population and in the clinically evaluable (CE) population. In study 9801, clinical success rates in the ITT population were 62.5% (165/264) in patients treated with CUBICIN and 60.9% (162/266) in patients treated with comparator drugs.

Clinical success rates in the CE population were 76.0% (158/208) in patients treated with CUBICIN and 76.7% (158/206) in patients treated with comparator drugs. In study 9901, clinical success rates in the ITT population were 80.4% (217/270) in patients treated with CUBICIN and 80.5% (235/292) in patients treated with comparator drugs. Clinical success rates in the CE population were 89.9% (214/238) in patients treated with CUBICIN and 90.4% (226/250) in patients treated with comparator drugs

S. aureus Bacteremia/Endocarditis

Adults with S. aureus Bacteremia/Endocarditis

The efficacy of CUBICIN in the treatment of adult patients with S. aureus bacteremia was demonstrated in a randomized, controlled, multinational, multicenter, open-label trial. In this trial, adult patients with at least one positive blood culture for S. aureus obtained within 2 calendar days prior to the first dose of study drug and irrespective of source were enrolled and randomized to either CUBICIN (6 mg/kg IV every 24h) or standard of care [an anti-staphylococcal semi-synthetic penicillin 2 g IV q4h (nafcillin, oxacillin, cloxacillin, or flucloxacillin) or vancomycin 1 g IV q12h, each with initial gentamicin 1 mg/kg IV every 8 hours for first 4 days]. Of the patients in the comparator group, 93% received initial gentamicin for a median of 4 days, compared with 1 patient.

The coprimary efficacy endpoints in the trial were the Adjudication Committee success rates at the Test of Cure visit (6 weeks after the last treatment dose) in the ITT and Per Protocol (PP) populations. The overall Adjudication Committee success rates in the ITT population were 44.2% (53/120) in patients treated with CUBICIN and 41.7% (48/115) in patients treated with comparator (difference = 2.4% [95% CI −10.2, 15.1]). The success rates in the PP population were 54.4% (43/79) in patients treated with CUBICIN and 53.3% (32/60) in patients treated with comparator (difference = 1.1% [95% CI −15.6, 17.8]

**CLINICAL STUDIES: Orbactiv/Kimyrsa**

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

A total of 1987 adults with clinically documented ABSSSI suspected or proven to be due to Gram-positive pathogens were randomized into two identically designed, randomized, doubleblind, multi-center, multinational, non-inferiority trials (Trial 1 and Trial 2) comparing a single 1,200 mg intravenous dose of oritavancin to intravenous vancomycin (1 g or 15 mg/kg every 12 hours) for 7 to 10 days. The primary analysis population (modified intent to treat, mITT) included all randomized patients who received any study drug. Patients could receive concomitant aztreonam or metronidazole for suspected Gram-negative and anaerobic infection, respectively. Patient demographic and baseline characteristics were balanced between treatment groups. Approximately 64% of patients were Caucasian and 65% were males. The mean age was 45 years and the mean body mass index was 27 kg/m2. Across both trials, approximately 60% of patients were enrolled from the United States and 27% of patients from Asia. A history of 17 diabetes was present in 14% of patients. The types of ABSSSI across both trials included cellulitis/erysipelas (40%), wound infection (29%), and major cutaneous abscesses (31%). Median infection area at baseline across both trials was 266.6 cm2 . The primary endpoint in both trials was early clinical response (responder), defined as cessation of spread or reduction in size of baseline lesion, absence of fever, and no rescue antibacterial drug at 48 to 72 hours after initiation of therapy

Another secondary efficacy endpoint in the two trials was investigator-assessed clinical success at post therapy evaluation at Day 14 to 24 (7 to 14 days from end of blinded therapy). A patient was categorized as a clinical success if the patient experienced a complete or nearly complete resolution of baseline signs and symptoms related to primary ABSSSI site (erythema, induration/edema, purulent drainage, fluctuance, pain, tenderness, local increase in heat/warmth) such that no further treatment with antibacterial drugs was needed.

## HCPCS Code

| HCPCS code | Description |
|---|---|
| J2407 | Injection, Oritavancin (Orbactiv) 10mg |
| J2406 | Injection, Oritavancin (Kimyrsa) 10mg |
| J0875 | Injection, Dalbavancin (Dalvance) 5mg |
| J0878 | Injection, Daptomycin (Cubicin 1mg |

## Acronyms

ABSSSI = Acute bacterial skin and skin structure infections

cSSSI = Complicated skin and skin structure infections

LCD = Local Coverage Determinations

NCD = National Coverage Determinations

MRSA = Methicillin-resistant S. aureus

VRE = Vancomycin-resistant Enterococcus

## References


1. Dalvance (dalbavancin) injection for intravenous use [package insert]. Madison, NJ:Allergan USA, Inc; 2018.
2. Orbactiv (oritavancin) injection for intravenous use [package insert]. Lincolnshire, IL:Melinta Therapeutics, Inc; 2021
3. Cubicin (daptomycin for injection) for intravenous use [package insert]. WhitehouseStation, NJ: Merck&Co, Inc; 2022.
4. Kimyrsa (oritavancin) injection for intravenous use [package insert]. Lincolnshire, IL:Melinta Therapeutics, Inc; 2021
5. Dalvance® In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health,Greenwood Village, Colorado, USA. Available at:https://www.micromedexsolutions.com/ (accessed Mar 2023)
6. Cubicin® In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health,Greenwood Village, Colorado, USA. Available at:https://www.micromedexsolutions.com/ (accessed Mar 2023)
7. Orbactiv®/Kimyrsa In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health,Greenwood Village, Colorado, USA. Available at:https://www.micromedexsolutions.com/ (accessed Mar 2023)
8. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 Update by the Infectious Disease Society of America. IDSA guidelines. Clin Infect Dis. 2014; 59(2):e10-e52.

## Policy History/Revision Information

| Date Revised | Type of Changes Significant or Minor | List Significant Changes and/or Status of policy |
|---|---|---|
| 1/7/2019 | Significant | New coverage criteria created – E Stanley, Pharm.D. |
| 2/13/2020 | Minor | Updated references and added duration of therapy for Daptomycin in decreased kidney function. M Gaither, Pharm. D. |
| 5/18/2021 | Minor | Annual criteria revision. Updated to new standard formatting per new template. Updated references. Removed requirement for prescribed by a specialist. M. Dawood, Pharm.D. |
| 6/10/2021 | Minor | Annual Criteria revision. Removed specialist prescribing requirement Updated dosing table, references, and CPT information - A Lawal, PharmD |
| 3/8/2023 | Minor | Updated to add the drug Kimyrsa, added non FDA indications for Daptomycin, added additional information from the clinical studies - S. Muchando Pharm D |