Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Oritavancin diphosphate (Orbactiv®, Kimyrsa®)	MP-RX-FP-133-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Oritavancin diphosphate (Orbactiv®, Kimyrsa®),* a lipoglycopeptide antibacterial drug approved by the Food and Drug Administration (FDA) for the treatment of 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.

Background Information

Oritavancin diphosphate (Orbactiv®, Kimyrsa®), a semi-synthetic lipoglycopeptide antibiotic, is FDA-approved for treating Gram-positive bacterial infections in adults. Specifically, it's indicated for acute bacterial skin and skin structure infections (ABSSSIs) caused by susceptible Gram-positive organisms. Its activity spans various bacteria including *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). Notably, oritavancin shows limited activity against Gram-negative bacteria.

In order to minimize the emergence of drug-resistant bacteria and preserve the efficacy of Oritavancin-containing products, these drugs should only be utilized for the treatment or prevention of infections that are confirmed or highly suspected to be caused by bacteria susceptible to the drug.

Oritavancin is available as two different products, Orbactiv® and Kimyrsa®. Orbactiv® was the initial formulation approved by the FDA, requiring administration as a 3-hour intravenous infusion. A newer formulation, Kimyrsa®, was subsequently developed to allow for a 1-hour infusion and received FDA approval for ABSSSI treatment on March 12, 2021. Despite variations in dose strength, infusion duration, and preparation instructions between the two formulations, their clinical utility remains consistent.

Approved Indications

A. 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.

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Other Uses

i. None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J2406	Injection, oritavancin (Kimyrsa), 10 mg
J2407	Injection, oritavancin (Orbactiv), 10 mg

ICD-10	Description
A49.01	Methicillin susceptible *staphylococcus aureus,* unspecified site
A49.02	Methicillin resistant *staphylococcus aureus* infection, unspecified site
B95.62	*Staphylococcus aureus* as the cause of diseases classified elsewhere (methicillin resistant)
B95.61	*Staphylococcus aureus* as the cause of diseases classified elsewhere (methicillin susceptible)
B95.8	Unspecified *staphylococcus* as the cause of diseases classified elsewhere
A49.1	*Streptococcus* infection, unspecified site
B95.0–B95.2, B95.4	*Streptococcus*, as the cause of disease classified elsewhere
A46	Erysipelas
L08.0–L08.1, L08.81–L08.89, L08.9	Other local infections of skin and subcutaneous tissue
L03.211	Cellulitis of face
K12.2	Cellulitis and abscess of mouth
H05.011–H05.019	Cellulitis of orbit, abscess of orbit
H60.10–H60.13	Cellulitis of external ear
J34.0	Cellulitis and abscess of external nose
L03.221	Cellulitis of neck
L03.113–L03.114	Cellulitis of upper limb
L03.111–L03.114	Cellulitis of axilla and upper limb

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L03.011–L03.019	Cellulitis of finger
N61	Inflammatory disorders of breast (includes cellulitis/abscess breast)
L03.311–L03.316, L03.319	Cellulitis of trunk
L03.317	Cellulitis of buttock
L03.119	Cellulitis of unspecified part of limb
L03.115–L03.116	Cellulitis of lower limb
N48.22	Cellulitis of corpus cavernosum and penis
L03.031–L03.039	Cellulitis of toe
L03.811–L03.818	Cellulitis of other sites
L03.90	Cellulitis, unspecified
L02.01	Cutaneous abscess of face
H00.031–H00.039	Abscess and furuncle of eyelid
H60.00–H60.03	Abscess of external ear
K12.2	Submandibular abscess
L02.11	Cutaneous abscess of neck
L02.411–L02.414	Cutaneous abscess of axilla and upper limb
L02.511–L02.519	Cutaneous abscess of hand
L02.211–L02.219	Cutaneous abscess of trunk
L02.31	Cutaneous abscess of buttock
L02.419	Cutaneous abscess of limb, unspecified
L02.415–L02.416	Cutaneous abscess of lower limb
L02.611–L02.619	Cutaneous abscess of foot
N48.21	Abscess of corpus cavernosum and penis
N76.4	Abscess of vulva
K61.0–K61.4	Abscess of anal and rectal regions
L02.811–L02.818	Cutaneous abscess of other sites
L02.91	Cutaneous abscess, unspecified
L02.02	Furuncle of face
L02.12	Furuncle of neck
L02.421–L02.424	Furuncle of axilla, upper limb
L02.521–L02.529	Furuncle of hand
L02.221–L02.229	Furuncle of trunk
L02.32	Furuncle of buttock
L02.429	Furuncle of limb, unspecified
L02.425–L02.426	Furuncle of lower limb
L02.621–L02.629	Furuncle of foot
L02.821–L02.828	Furuncle of other sites
L02.92	Furuncle, unspecified
L02.03	Carbuncle of face

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J34.0	Carbuncle and furuncle of external nose
L02.13	Carbuncle of neck
L02.431–L02.434	Carbuncle of axilla, upper limb
L02.531–L02.539	Carbuncle of hand
L02.231–L02.239	Carbuncle of trunk
L02.33	Carbuncle of buttock
L02.439	Carbuncle of limb, unspecified
L02.435–L02.436	Carbuncle of lower limb
L02.631–L02.639	Carbuncle of foot
L02.831–L02.838	Carbuncle of other sites
L02.93	Carbuncle, unspecified

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Oritavancin diphosphate (Orbactiv®, Kimyrsa®)

A. Criteria For Initial Approval *Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. The patient has been diagnosed with an acute bacterial skin or skin structure infection (ABSSSI), caused by a gram-positive organism; **AND**

A. The infection is confirmed or suspected to be caused by one of the following Gram-positive organisms, based on clinical judgment or culture and susceptibility testing: *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), *Enterococcus faecalis* (vancomycin-susceptible isolates only).

B. Criteria For Continuation of Therapy

i. Continuation of therapy is not applicable, as oritavancin is indicated for single-dose administration.

C. Authorization Duration

i. Initial Approval Duration: One time approval.

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ii. Reauthorization Approval Duration: Not applicable.

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Oritavancin (Orbactiv®, Kimyrsa®) is not recommended for treating infections in other areas, such as urinary tract infections, or non-Gram-Positivie ABSSSI.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Orbactiv® 400 mg SDV	1,200 mg administered as a single dose by intravenous infusion over 3 hours.
Kimyrsa® 1,200 mg SDV	1,200 mg administered as a single dose by intravenous infusion over 1 hour.
Exceptions	
None	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. Jackson BT, Cluck DB, Henao-Martínez AF, Chastain DB. Kimyrsa and Orbactiv - A Tale of Two Formulations. Drug Des Devel Ther. 2023 Mar 9;17:737-742. doi: 10.2147/DDDT.S324285. PMID: 36923104; PMCID: PMC10010140

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/18/2024	Added "diphosphate" to policy name. Modified criteria for initial approval to align with approved indication. Updated dosage form for each drug and removed age criteria from the quantity limits table. Wording and formatting changes. Added federal statement. Coding Reviewed: no changes.	3/20/2025	4/2/2025
Policy Inception 01/25/2024	New Medical Policy creation	3/25/2024	6/28/2024