

Cubicin (daptomycin) Policy Number: C10467-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
4/1/2017	11/18/2020	1/26/2022
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
J0878-injection, daptomycin, 1mg	RxPA	Q1 2021 20210127C10467-A

PRODUCTS AFFECTED:

Cubicin (daptomycin)

DRUG CLASS:

Cyclic Lipopeptides

ROUTE OF ADMINISTRATION:

Intravenous

PLACE OF SERVICE:

Specialty Pharmacy, Buy and Bill

The recommendation is that medications in this policy will be for medical benefit coverage and the product is administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the therapy/member meets the Site of Care exceptions. (See appendix for excerpt from Specialty Medication Administration Site of Care Policy)

AVAILABLE DOSAGE FORMS:

Cubicin RF SOLR 500MG, Cubicin SOLR 500MG, Daptomycin For IV Soln 500 MG

FDA-APPROVED USES:

CUBICIN is indicated for the treatment of:

- Complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age)
- Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis
- Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).

Limitations of Use: CUBICIN is not indicated for the treatment of pneumonia. CUBICIN is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*. CUBICIN is not recommended in pediatric patients younger than one year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of CUBICIN and other antibacterial drugs, CUBICIN should be used to treat infections that are proven or strongly suspected to be caused by bacteria

COMPENDIAL APPROVED OFF-LABELED USES:

Septic arthritis (alternative agent), Osteomyelitis and/or discitis (alternative agent)

COVERAGE CRITERIA: INITIAL AUTHORIZATION**DIAGNOSIS:**

Complicated skin and skin structure infections (cSSSI), Staphylococcus aureus bloodstream infections (bacteremia), infective endocarditis, Staphylococcus aureus bloodstream infections (bacteremia), Septic arthritis (alternative agent), Osteomyelitis and/or discitis (alternative agent)

REQUIRED MEDICAL INFORMATION:**A. FOR ALL INDICATIONS:**

1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported.
AND
2. (a) Documentation of FDA labeled contraindication to Vancomycin
OR
(b) Documentation of inadequate treatment response, intolerance, or non-susceptibility report for the current infection to Vancomycin
OR
(c) Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with Vancomycin

DURATION OF APPROVAL:

Initial authorization: total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication
Continuation of therapy: NA; Members must meet the initial approval criteria.

QUANTITY:

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:

Age ≥ 1 year for cSSSI and Staphylococcus aureus blood stream infections (bacteremia)
18 years of age and older for Staphylococcus aureus blood stream infections in adult patients with right sided endocarditis

CONTINUATION OF THERAPY:

NA

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cubicin (daptomycin) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Cubicin (daptomycin) is not indicated for the treatment of pneumonia. Cubicin (daptomycin) is not indicated for the treatment of left-sided infective endocarditis due to S. aureus. Cubicin (daptomycin) is not recommended in pediatric patients younger than one year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs

OTHER SPECIAL CONSIDERATIONS:

None

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BACKGROUND:

None

APPENDIX:

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at a non-hospital facility based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Cubicin (daptomycin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2020
2. Baddour LM, Wilson WR, Bayer AS, et al; American Heart Association Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease of the Council on Cardiovascular Disease in the Young, Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and Stroke Council. Infective endocarditis in adults: diagnosis, antimicrobial therapy, and management of complications: a scientific statement for healthcare professionals from the American Heart Association [published

- correction appears in Circulation. 2015;132(17):e215]. Circulation. 2015;132(15):1435-1486. doi: 10.1161/CIR.0000000000000296.
3. Berbari EF, Kanj SS, Kowalski TJ, et al; Infectious Diseases Society of America. 2015 Infectious Diseases Society of America (IDSA) clinical practice guidelines for the diagnosis and treatment of native vertebral osteomyelitis in adults. Clin Infect Dis. 2015;61(6):e26-e46.
 4. Mermel LA, Allon M, Bouza E, et al: Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis 2009; 49:1-45.
 5. Liu C, Bayer A, Cosgrove SE, et al: Clinical practice guidelines by the infectious disease's society of america for the treatment of methicillin-resistant Staphylococcus aureus infections in adults and children. Clin Infect Dis 2011; 52(3):e18-e55.
10.1161/CIR.0000000000000296
 6. Tunkel AR, Hasbun R, Bhimraj A, et al. 2017 Infectious Diseases Society of America's clinical practice guidelines for healthcare-associated ventriculitis and meningitis. Clin Infect Dis. 2017;64(6):e34-e65