Effective Date: 04/01/2017
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C10467-A

Cubicin (daptomycin)

PRODUCTS AFFECTED

Cubicin (daptomycin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

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

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:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

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 thecurrent infection to Vancomycin
   OR
   (c) Prescriber provides detailed medical necessity rationale against outpatient parenteral antimicrobial therapy with Vancomycin
   OR
   (d) Request is for a continuation of therapy that was started at an in-patient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER RECOMMENDED DURATION OF THERAPY; START AND END DATE]

CONTINUATION OF THERAPY:
NA

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.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultationnotes must be submitted within initial request and reauthorization requests]

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

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

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Cyclic Lipopeptides

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)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0878	injection, daptomycin,1mg

AVAILABLE DOSAGE FORMS:
Cubicin RF SOLR 500MG, Cubicin SOLR 500MG, Daptomycin For IV Soln 500 MG

REFERENCES

1. Cubicin (daptomycin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp;March 2021.
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