Original Effective Date: 04/01/2017
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C10467-A

Cubicin (daptomycin)

PRODUCTS AFFECTED

Cubicin (daptomycin), 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 (MSSA) bloodstream infections (bacteremia), infective endocarditis, Staphylococcus aureus bloodstream infections (MRSA) (bacteremia), Septic arthritis (alternative agent), Osteomyelitis and/or discitis (alternative agent), vancomycin-resistant enterococci, MRSA-associated prosthetic device infections, MRSA-associated spinal implant infections, empiric treatment of febrile neutropenia, treatment of intraabdominal infections, including peritonitis, appendicitis, intraabdominal abscess, spontaneous bacterial peritonitis, and peritoneal dialysis-related peritonitis

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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a

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mandatory generic and that generic drugs will be dispensed whenever available.

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, serious side effects, 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
   OR
   (d) Request is for continuation of therapy that was started at an inpatient 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:
N/A; Each new infection treatment should be a new review

DURATION OF APPROVAL:
Initial authorization: Total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication, Continuation of therapy: N/A

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

AGE RESTRICTIONS:
≥ 1 year for cSSSI and Staphylococcus aureus blood stream infections (bacteremia)
18 years of age and older for Staphylococcus aureus blood stream infections 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

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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) 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)
- Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis caused by methicillin-susceptible and methicillin-resistant isolates
- 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), vancomycin-resistant enterococci, MRSA-associated prosthetic device infections, MRSA-associated spinal implant infections, empiric treatment of febrile neutropenia, treatment of intraabdominal infections, including peritonitis, appendicitis, intraabdominal abscess, spontaneous bacterial peritonitis, and peritoneal dialysis-related peritonitis

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Daptomycin is a novel lipopeptide antibiotic with coverage of gram-positive organisms, e.g., Staph. aureus, enterococci and streptococci, including activity against MRSA and VRE. It is FDA approved for complicated skin and soft tissue infections (cSSSI) caused by gram-positive cocci, Staph. Aureus bacteremia and right-sided Staph. Aureus endocarditis. Daptomycin is inactivated by pulmonary surfactant and must not be used for pneumonia.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cubicin (daptomycin) are considered experimental/investigational and therefore will follow Molina's Off- Label policy. Contraindications to Cubicin (daptomycin) include: known hypersensitivity to daptomycin.

OTHER SPECIAL CONSIDERATIONS:

Clostridioides difficile–associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis [see Adverse Reactions. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile. C. difficile produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of C. difficile cause increased morbidity and mortality, since these infections

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can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. 9 If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg
J0873	Injection, daptomycin (xellia) not therapeutically equivalent to J0878, 1 mg
J0874	Injection, daptomycin (baxter), not therapeutically equivalent to J0878, 1 mg
J0877	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg
J0878	Injection, daptomycin,1mg

AVAILABLE DOSAGE FORMS:
Cubicin RF SOLR 500MG
Cubicin SOLR 500MG
DAPTOmycin SOLR 350MG
DAPTOmycin SOLR 500MG
DAPTOmycin-Sodium Chloride SOLN 1000-0.9MG/100ML-%
DAPTOmycin-Sodium Chloride SOLN 350-0.9MG/50ML-%
DAPTOmycin-Sodium Chloride SOLN 500-0.9MG/50ML-%
DAPTOmycin-Sodium Chloride SOLN 700-0.9MG/100ML-%

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information References	Q1 2025
REVISION- Notable revisions: Background Other Special Considerations Coding/Billing Information Available Dosage Forms	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Prescriber Requirements FDA-Approved Uses Compendial Approved Off-Labeled Uses Contraindications/Exclusions/Discontinuation HCPCS Code and Description Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file

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