Clinical Policy: Daptomycin (Cubicin, Cubicin RF, Dapzura RT)

Reference Number: LA.PHAR.351
Effective Date: 02.03.24
Last Review Date: ~~06.20.23~~05.07.24 Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Daptomycin for injection (Cubicin®, Cubicin® RF, Dapzura™ RT) is a lipopeptide antibacterial.

FDA Approved Indication(s)
Cubicin/Cubicin RF/Dapzura RT is indicated for the treatment of:

- Adult and pediatric patients (1 to 17 years of age) with complicated skin and skin structure infections caused by susceptible isolates of the following gram-positive bacteria:
  - *Staphylococcus aureus* (including methicillin-resistant isolates);
  - *Streptococcus pyogenes;*
  - *Streptococcus agalactiae;*
  - *Streptococcus dysgalactiae* subspecies *equisimilis,* and;
  - *Enterococcus faecalis* (vancomycin-susceptible isolates only).
- Adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia), including adult patients with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.
- Pediatric patients (1 to 17 years of age) with *Staphylococcus aureus* bloodstream infections (bacteremia).

Limitation(s) of use:

- Cubicin/Cubicin RF/Dapzura RT is not indicated for:
  - The treatment of pneumonia.
  - The treatment of left-sided infective endocarditis due to *Staphylococcus aureus*. The clinical trial of Cubicin/Cubicin RF/Dapzura RT in adult patients with *Staphylococcus aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor. Cubicin/Cubicin RF/Dapzura RT has not been studied in patients with prosthetic valve endocarditis.
- Cubicin/Cubicin RF/Dapzura RT is not recommended in pediatric patients younger than 1 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/Cubicin RF/Dapzura RT and other antibacterial drugs, Cubicin/Cubicin RF/Dapzura RT should be used to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. When culture and susceptibility information is available, it should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local

epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Empiric therapy may be initiated while awaiting test results.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Cubicin, Cubicin RF, and Dapzura RT are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Skin and Skin Structure Infection (must meet all)**:**

1. Diagnosis of complicated skin and skin structure infection caused by susceptible isolates of any of the following gram-positive bacteria:
   a. *Staphylococcus aureus*;
   b. *Streptococcus pyogenes;*
   c. *Streptococcus agalactiae;*
   d. *Streptococcus dysgalactiae* subsp. *equisimilis;*
   e. *Enterococcus faecalis* (vancomycin-susceptible isolates only);
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age ≥ 1 year;
4. Failure of vancomycin, unless contraindicated, clinically significant adverse effects are experienced, or culture and sensitivity report indicates that the relevant pathogen is not susceptible to vancomycin;
5. If request is for brand Cubicin/Cubicin RF/Dapzura RT, member must use generic daptomycin, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed any of the following:
   a. Age 1 to < 2 years: 10 mg per kg per day;
   b. Age 2 to 6 years: 9 mg per kg per day;
   c. Age 7 to 11 years: 7 mg per kg per day;
   d. Age 12 to 17 years: 5 mg per kg per day;
   e. Age ≥ 18 years: 4 mg per kg per day.

Approval duration: Up to 14 days

B. Bloodstream Infection and Infective Endocarditis (must meet all)**:**

1. Diagnosis of bloodstream infection (bacteremia) [including infective endocarditis] caused by *Staphylococcus aureus;*
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age ≥ 1 year;
4. If concurrent infective endocarditis, age ≥ 18 years;
5. If request is for left-sided infective endocarditis (off-label), failure of vancomycin, unless contraindicated, clinically significant adverse effects are experienced, or culture and sensitivity report indicates that the relevant pathogen is not susceptible to vancomycin;

6. If request is for brand Cubicin/Cubicin RF/Dapzura RT, member must use generic daptomycin, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed any of the following:
   a. Age 1 to 6 years: 12 mg per kg per day;
   b. Age 7 to 11 years: 9 mg per kg per day;
   c. Age 12 to 17 years: 7 mg per kg per day;
   d. Age ≥ 18 years: 6 mg per kg per day or 10 mg per kg per day for infective endocarditis.

Approval duration: Up to 42 days

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Skin and Skin Structure Infection (must meet all)**:**
1. Currently receiving medication;
2. Member has not yet received 14 days of therapy;
3. If request is for brand Cubicin/Cubicin RF/Dapzura RT, member must use generic daptomycin, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed any of the following:
   a. Age 1 to < 2 years: 10 mg per kg per day;
   b. Age 2 to 6 years: 9 mg per kg per day;
   c. Age 7 to 11 years: 7 mg per kg per day;
   d. Age 12 to 17 years: 5 mg per kg per day;
   e. Age ≥ 18 years: 4 mg per kg per day.

Approval duration: Up to 14 days

B. Bloodstream Infection and Infective Endocarditis (must meet all)**:**
1. Currently receiving medication;
2. Member has not yet received 42 days of therapy;
3. If request is for brand Cubicin/Cubicin RF/Dapzura RT, member must use generic daptomycin, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed any of the following:
   a. Age 1 to 6 years: 12 mg per kg per day;
   b. Age 7 to 11 years: 9 mg per kg per day;
   c. Age 12 to 17 years: 7 mg per kg per day;

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d. Age ≥ 18 years: 6 mg per kg per day or 10 mg per kg per day for infective endocarditis.

Approval duration: Up to 42 days

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents;

B. Treatment of pneumonia.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
vancomycin (Vancocin®)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to daptomycin
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Complicated skin and skin structure infections	Pediatrics: 1 to < 2 years: 10 mg/kg/day 2 to 6 years: 9 mg/kg/day 7 to 11 years: 7 mg/kg/day 12 to 17 years: 5 mg/kg/day Adults: ≥ 18 years: 4 mg/kg/day Duration of therapy: Up to 14 days	10 mg/kg/day for up to 14 days

Indication	Dosing Regimen	Maximum Dose
Bloodstream infection	Pediatrics: 1 to 6 years: 12 mg/kg/day 7 to 11 years: 9 mg/kg/day 12 to 17 years: 7 mg/kg/day Adults: ≥ 18 years: 6 mg/kg/day Duration of therapy: Up to 42 days	12 mg/kg/day for up to 42 days
Infective endocarditis	Adults: ≥ 18 years: 6 mg/kg/day Duration of therapy: Up to 42 days	~~6~~10 mg/kg/day for up to 42 days

VI. Product Availability

Drug Name	Availability
Daptomycin for injection (Cubicin)	Lyophilized cake in a single-dose 10 mL vial containing 500 mg of daptomycin. *Reconstituted with 0.9% sodium chloride.*
Daptomycin for injection (Cubicin RF)	Lyophilized powder in a single-dose 10 mL vial containing 500 mg of daptomycin. *Reconstituted with Sterile Water for Injection or Bacteriostatic Water for Injection.*
Daptomycin for injection (Dapzura RT)	Premixed frozen isosmotic solution: 350 mg/50 mL (7 mg/mL), 500 mg/50 mL (10 mg/mL), 700 mg/100 mL (7 mg/mL), 1,000 mg/100 mL (10 mg/mL) in single-dose Galaxy container

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VII. References

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5. 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 Diseases Society of America. Clinical Infectious Diseases. April 2014:59(2):10-52.
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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0873	Injection, daptomycin (xellia) not therapeutically equivalent to J0878, 1 mg
J0874	Injection, daptomycin (baxter), not therapeutically equivalent to J0878, 1 mg
J0878	Injection, daptomycin, 1 mg
J0877	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.20.23	01.03.24
Annual review; clarified dosing for infective endocarditis for ages 18 and older; added HCPCS codes [J0873, J0874].	05.07.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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