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

Reference Number: PA.CP.PHAR.351
Effective Date: 10/2018
Last Review Date: 07/2023

Coding Implications
Revision Log

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 PA Health & Wellness® 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 or 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 one of the following (a-f):
   a. Age 1 to < 2 years: ≤ 10 mg/kg/day;
   b. Age 2 to 6 years: ≤ 9 mg/kg/day;
   c. Age 7 to 11 years: ≤ 7 mg/kg/day;
   d. Age 12 to 17 years: ≤ 5 mg/kg/day;
   e. Age ≥ 18 years: ≤ 4 mg/kg/day;
   f. Dose is supported by nationally recognized compendia or peer-reviewed medical literature.

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 one of the following (a-e):
   a. Age 1 to 6 years: ≤ 12 mg/kg/day;
   b. Age 7 to 11 years: ≤ 9 mg/kg/day;

c. Age 12 to 17 years: ≤ 7 mg/kg/day;
d. Age ≥ 18 years: ≤10 mg/kg/day:
e. Dose is supported by nationally recognized compendia or peer-reviewed medical literature.

Approval duration: Up to 42 days

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 one of the following (a-f):
   a. Age 1 to < 2 years: ≤ 10 mg/kg/day;
   b. Age 2 to 6 years: ≤ 9 mg/kg/day;
   c. Age 7 to 11 years: ≤ 7 mg/kg/day;
   d. Age 12 to 17 years: ≤ 5 mg/kg/day;
   e. Age ≥ 18 years: ≤ 4 mg/kg/day:
   f. Dose is supported by nationally recognized compendia or peer-reviewed medical literature.

Approval duration: Up to 14 days

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 one of the following (a-e):
   a. Age 1 to 6 years: ≤ 12 mg/kg/day;
   b. Age 7 to 11 years: ≤ 9 mg/kg/day;
   c. Age 12 to 17 years: ≤ 7 mg/kg/day;
   d. Age ≥18 years: ≤ 10 mg/kg/day;
   e. Dose is supported by nationally recognized compendia or peer-reviewed medical literature.

Approval duration: Up to 42 days

C. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53;

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
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:10 mg/kg/day Duration of therapy: Up to 42 days	12 mg/kg/day for up to 42 days

Indication	Dosing Regimen	Maximum Dose
Infective endocarditis	Adults: ≥ 18 years: 10 mg/kg/day Duration of therapy: Up to 42 days	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

VII. References

1. Cubicin Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc. November 2022. Available at: http://www.merck.com/product/usa/pi_circulars/c/cubicin/cubicin_pi.pdf. Accessed April 20, 2023.
2. Cubicin RF Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc. November 2022. Available at: http://www.merck.com/product/usa/pi_circulars/c/cubicin_rf/cubicin_rf_pi.pdf. Accessed April 20, 2023.
3. Dapzura RT Prescribing Information. Deerfield, IL: Baxter Healthcare Corporation. February 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213645s001lbl.pdf. Accessed March 20, 2023.
4. Clinical Pharmacology [database online]. Elsevier, Inc.; 2022. Available at: https://www.clinicalkey.com/pharmacology/.
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.
6. Baddour L, Wilson W, Bayer A. Infective Endocarditis in Adults: Diagnosis, Antimicrobial Therapy, and Management of Complications. AHA scientific statement. 2015;132:1435-1486.

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
J0878	Injection, daptomycin, 1 mg
J0877	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/2018	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	072019	
3Q 2020 annual review: added age limit to SSSI indication; references reviewed and updated.	07/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	
3Q 2022 annual review: added requirement for use of generic daptomycin if request if for brand Cubicin/Cubicin RF; references reviewed and updated.	07/2022	
RT4: added new dosage form Dapzura RT to policy.	04/2023	
3Q 2023 annual review: added requirements to allow use after failure of vancomycin per AHA 2015 Infective Endocarditis Scientific Statement; added HCPCS code J0877; references reviewed and updated.	07/2023	