Clinical Policy: Daptomycin (Cubicin, Cubicin RF)

Reference Number: PA.CP.PHAR.351
Effective Date: 10.17.18
Last Review Date: 07/17/19

Coding Implications
Revision Log

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

FDA Approved Indication(s)
Cubicin/Cubicin RF is a lipopeptide antibacterial 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 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 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 has not been studied in patients with prosthetic valve endocarditis.
- Cubicin/Cubicin RF 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 and other antibacterial drugs, Cubicin/Cubicin RF should be used to treat 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 health plans affiliated with PA Health & Wellness® that Cubicin and Cubicin RF 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. 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;
4. Dose does not exceed any of the following:
   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.

Approval duration: Up to 14 days

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

1. Diagnosis of bloodstream infection (bacteremia) caused by *Staphylococcus aureus;*
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age ≥ 1 year;
4. If concurrent infective endocarditis (right-sided; native valve), age ≥ 18 years;
5. Dose does not exceed any of the following:
   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: 6 mg/kg/day.

Approval duration: Up to 42 days

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business 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 Pennsylvania Health and 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 a dose increase, new dose does not exceed any of the following:
   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.

Approval duration: Up to 14 days

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

1. Currently receiving medication via Pennsylvania Health and 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 a dose increase, new dose does not exceed any of the following:
   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: 6 mg/kg/day.

Approval duration: Up to 42 days

C. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and 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;
C. Treatment of left-sided infective endocarditis due to *Staphylococcus aureus.*

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
Not applicable

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: 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 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.*

VII. References

1. Cubicin Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc. September 2017. Available at http://www.merck.com/product/usa/pi_circulars/c/cubicin/cubicin_pi.pdf. Accessed June 2018.
2. Cubicin RF Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc. September 2017. Available at http://www.merck.com/product/usa/pi_circulars/c/cubicin_rf/cubicin_rf_pi.pdf. Accessed June 2018.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	