RX.PA.045.MPC Cubicin (daptomycin)

The purpose of this policy is to define the prior authorization process for Cubicin® (daptomcyin)

Cubicin® (daptomycin) is indicated for the treatment of complicated skin and skin structure infections (cSSSI) in adult patients and pediatric patients (1 to 17 years of age). Cubicin® (daptomycin) is also indicated for the treatment of *Staphylococcus aureus* bloodstream infections (bacteremia) including those with right-sided infective endocarditis in adult patients.

PROCEDURE

A. Initial Authorization Criteria:

1. Complicated Skin and Skin Structure Infection (cSSSI):

- Adult and pediatric members (≥1 years old)
  AND
- Must have documentation of a diagnosis of a complicated skin and skin structure infection caused by susceptible isolates of the following Gram-positive bacteria:
  - *Staphylococcus aureus (*includes methicillin-resistant isolates)
  - *Streptococcus pyogenes*
  - *Streptococcus agalactiae*
  - *Streptococcus dysgalactiae* subsp. *Equisimilis*
  - *Enterococcus faecalis* (vancomycin-susceptible isolates only)

  AND
- Must have recent culture and sensitivity report to confirm susceptibility to Cubicin
  AND
- Trial and failure with IV Vancomycin and oral Linezolid or documented intolerance/contraindication to Vancomycin and Linezolid OR culture and sensitivity report that indicates resistance to Vancomycin and Linezolid

2. Bacteremia and right-sided infective endocarditis:

- Adult and pediatric members (≥1 years old)
  AND
- Must have documentation of blood stream infection (bacteremia), including those with right-sided infected endocarditis, caused by *Staphylococcus aureus*:
  - Includes methicillin-susceptible and methicillin-resistant isolates

  AND
- Must have recent culture and sensitivity report to confirm susceptibility to Cubicin
  AND

- Trial and failure with IV Vancomycin and oral Linezolid or documented intolerance/contraindication to Vancomycin and Linezolid OR culture and sensitivity report that indicates resistance to Vancomycin and Linezolid

B. Approved Dosing and Duration of Approval:

- Complicated skin and skin structure:
  - Pediatric (1 year old): 10mg/kg/day
  - Pediatric (2-6 years old): 9mg/kg/day
  - Pediatric (7-11 years old): 7mg/kg/day
  - Pediatric (12-17 years old): 5mg/kg/day
  - Adult (18 years and older): 4mg/kg/day

  Duration of Approval: 14 days

- Bacteremia and right-sided infective endocarditis (*Staphylococcus aureus*):
  - Pediatric (1-6 years old): 12mg/kg/day
  - Pediatric (7-11 years old): 9mg/kg/day
  - Pediatric (12-17 years old): 7mg/kg/day
  - Adult (18 years and older): 6mg/kg/day

  Duration of Approval: 42 days

C. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

D. Cubicin will be considered investigational or experimental for any other use and will not be covered.

E. Reauthorization Criteria:

Not applicable – each occurrence requires a new prior authorization

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Complicated skin and skin structure infections: 14 days Bacteremia: 42 days Infective endocarditis: 42 days
Reauthorization	N/A

Codes:

Code	Description
J0878	Injection, daptomycin, 1 mg

REFERENCES

1. Cubicin [package insert]. Madison, NJ: Allergan USA, Inc.; March 2017.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
P&T Review	*11/2021*