

Committee to Evaluate Drugs (CED)

Recommendations and Reasons

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Daptomycin

Product: daptomycin (Cubicin®)

Class of Drugs: antibiotic

Reason for Use: bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections

Manufacturer: Sunovion Pharmaceuticals Canada Inc.

Date of Review: April 9, 2014

CED Recommendation

The CED recommended daptomycin (Cubicin®) be funded for the treatment of methicillin-resistant *Staphylococcus aureus* (MRSA) bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections according to specific criteria. Although there are no randomized controlled trials evaluating the use of daptomycin for these indications, available data and Infectious Diseases Society of America (IDSA) clinical practice guidelines support that daptomycin is effective for these types of infections, for which treatment options are limited.

Executive Officer Decision*

Based on the CED's recommendation and an agreement with the manufacturer, the Executive Officer decided to fund daptomycin (Cubicin®) for treatment of MRSA-related bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections according to specific criteria.

* This information is current as of the posting date of the document. For the most up-to-date information on Executive Officer decision and funding status, see: www.health.gov.on.ca/en/pro/programs/drugs/status_single_source_subm.aspx.

Funding Status*

Funded through the Ontario Drug Benefit's Exceptional Access Program according to specific criteria.

(EAP criteria can be found at: http://www.health.gov.on.ca/en/pro/programs/drugs/eap_criteria.aspx)

Highlights of Recommendation:

- Daptomycin is an antibiotic used to treat various types of infections. This review considered the use of daptomycin for bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in patients who cannot use vancomycin (another antibiotic).
- There are no randomized controlled trials evaluating the use of daptomycin for the indications under review.
- A number of small retrospective studies suggest daptomycin and vancomycin are similar in effectiveness for treating bone and joint infections.
- IDSA practice guidelines recommend daptomycin as an alternative treatment to vancomycin for a variety of MRSA infections, including bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and complicated skin and skin structure infections (cSSSI). Diabetic foot infections are a type of cSSSI.
- There are limited treatment options for patients with bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) or diabetic foot infections who cannot use vancomycin.

Background:

Methicillin-resistant *Staphylococcus aureus* (MRSA) bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections are usually treated with vancomycin, daptomycin or linezolid.

Daptomycin is already funded through the Ontario Drug Benefit's Exceptional Access Program for various types of infections. This review assessed the expanded funding of daptomycin for bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections caused by MRSA in patients who cannot use vancomycin.

Detailed Discussions:

- For this evaluation, the CED considered:
 - Information in the manufacturer's submission.
 - (No patient submission was received for this review.)
- IDSA guidelines recommend daptomycin as an alternative treatment to vancomycin for a variety of methicillin-resistant *Staphylococcus aureus* (MRSA) infections, including complicated skin and skin structure infections (cSSSI) and bone and joint infections

(including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections).

- There are no randomized controlled trials evaluating the use of daptomycin for MRSA bone and joint infections and diabetic foot infections.
- Based on small studies, which are primarily retrospective in nature, daptomycin and vancomycin appear to be similar in efficacy for treating bone and joint infections.
- Daptomycin is dosed once daily which facilitates outpatient therapy through central infusion centres or repeated emergency department visits. Vancomycin and linezolid are dosed twice daily.
- Daptomycin costs \$179.00 per day. The manufacturer did not conduct an economic analysis on the use of daptomycin in patients who cannot take vancomycin. The cost-effectiveness of daptomycin in this setting is unknown.
- Overall, although there are no robust data from randomized controlled trials supporting the use of daptomycin for bone and joint infections (including osteomyelitis, septic arthritis, device-related osteoarticular or prosthetic joint infections) and diabetic foot infections caused by MRSA, small retrospective studies and the IDSA guidelines suggest that daptomycin is similar to vancomycin in efficacy for these types of infections. Furthermore, treatment options are limited for the clinical settings under consideration.

Committee to Evaluate Drugs (CED)

The Committee to Evaluate Drugs (CED) is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

www.health.gov.on.ca/en/pro/programs/drugs/