## Ontario Public Drug Programs Drug Submission Status

Generic Name: daptomycin

**Brand Name: Cubicin** 

Strength: 500mg/10mL injection

Manufacturer: Cubist Pharmaceuticals, Inc.

Indication: For the treatment of patients with Staphylococcus aureus (SA) bloodstream infection including right-sided SA infective endocarditis infection caused by MRSA who are intolerant, contraindicated or have failed to respond adequately to vancomycin

Rapid Review: Not Requested

| Submission Type:                   | Date Submission Received: | Date Submission<br>Deemed<br>Complete: | Review Status:       | Funding Status:  |
|------------------------------------|---------------------------|--|----------------------|--|
| First Review: (Initial Submission) | 04/10/2013                | 06/02/2014                             | EO decision rendered | Funding considered<br>through the<br>Exceptional Access<br>Program (EAP) |

## Rapid Review:

Details of the Rapid Review process can be found at:

Rapid Review Process

## **Review Status:**

- Screening Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.
- Submission incomplete Manufacturer did not meet the necessary requirements to allow review to proceed.



- Submission complete & under review Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed A recommendation was made by the CED.
- Ontario Steering Committee for Cancer Drugs (OSCCD) review completed-A recommendation was made by the OSCCD.
- Executive Officer (EO) decision rendered.

## **Funding Status:**

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at:

The CED recommendation and the EO decision

Updated: November 24, 2015