About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

<table>
<thead>
<tr>
<th>Drug</th>
<th>fidaxomicin</th>
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</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Dificid™</td>
</tr>
<tr>
<td>Dosage Form(s)</td>
<td>200 mg tablet</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Cubist Pharmaceuticals Canada Inc. (formerly Optimer Pharmaceuticals Canada Inc.)</td>
</tr>
</tbody>
</table>

Submission Review

- Use Reviewed: For the treatment of *Clostridium difficile* infection (CDI)
- Common Drug Review (CDR): CDR recommended to: Do not list at the submitted price. Visit CDR website for more details: [http://www.cadth.ca/media/cdr/complete/cdr_complete_Dificid_December_21_12.pdf](http://www.cadth.ca/media/cdr/complete/cdr_complete_Dificid_December_21_12.pdf)

Drug Benefit Council (DBC)

DBC met on March 11, 2013. DBC considered various inputs including: the final review completed by the Common Drug Review (CDR) on December 19, 2012, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC); Health Authority Input; Clinical Practice Reviews from two Specialists, Manufacturer comments, infection control data and a pre-printed order from Vancouver Coastal Health (VCH), responses to Patient Input Questionnaires from two patients, one caregiver, two patient groups and a Budget Impact Analysis.

Drug Coverage Decision

- Limited Coverage Benefit

Date

- February 25, 2014

Reason(s)

- Drug coverage decision is generally consistent with the DBC recommendation. The Limited Coverage criteria were developed with consideration of input from infectious disease specialists and Health Authorities.
  - For the studied patient population, fidaxomicin was similar to vancomycin with respect to treatment of CDI, but may have longer time to recurrence of CDI and more patients with overall cure.
  - There is a lack of evidence for the role of fidaxomicin in the treatment of recurrent CDI, treatment in patients with severe, complicated CDI; and in patients with both underlying inflammatory bowel diseases and CDI.
  - Based on economic considerations and the product price, fidaxomicin is more costly than metronidazole and vancomycin.
  - On balance of all of the considerations, the Ministry has decided to provide fidaxomicin coverage on a limited but practical basis, in patients with severe disease when vancomycin is not an option and prescribed by infectious disease specialists.
The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council gives advice to the Ministry. The Council looks at:

- advice from a national group called the Common Drug Review
- whether the drug is safe and effective
- whether it is a good value for the people of B.C. and the drugs cost
- the ethics of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a decision based on many factors, including:

- advice from the Council
- drugs used to treat similar medical conditions that B.C. PharmaCare already covers
- the overall cost of covering the drug


To find out more about the Pharmaceutical Services Division and the PharmaCare program, visit www.health.gov.bc.ca/pharmacare.

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.