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>vedolizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Entyvio™</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>300 mg/vial powder for concentrate for solution for infusion</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Takeda Canada Inc.</td>
</tr>
<tr>
<td>Submission Type</td>
<td>New Submission</td>
</tr>
<tr>
<td>Use Reviewed</td>
<td>Crohn’s Disease</td>
</tr>
<tr>
<td>Common Drug Review (CDR)</td>
<td>Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions. Visit the CDR website for more details: <a href="http://www.cadth.ca/sites/default/files/cdr/complete/SR0487_complete_Entyvio-Oct-31-16.pdf">www.cadth.ca/sites/default/files/cdr/complete/SR0487_complete_Entyvio-Oct-31-16.pdf</a></td>
</tr>
</tbody>
</table>

Provincial Review

The Drug Benefit Council (DBC) now screens drug submissions under review by the CDR to determine whether or not a full DBC review is necessary, based on past DBC reviews, recommendations, and existing PharmaCare coverage. If a full DBC review is determined to not be required, the Ministry’s drug coverage decision will be based on the Canadian Drug Expert Committee (CDEC) recommendation and an internal review only. The DBC screened vedolizumab on July 4, 2016. The DBC advised that because vedolizumab has a similar place in therapy to some of the other biologic drugs used for the treatment of Crohn’s Disease, the Ministry may accept the CDEC’s recommendation for vedolizumab.

Drug Coverage Decision

Limited Coverage Benefit. Access the vedolizumab criteria from www.gov.bc.ca/pharmacarespecialauthority

Date

May 2, 2017

Reasons

Drug coverage decision is consistent with the CDEC recommendation.

- The drug demonstrated some advantage over placebo with respect to clinical remission of the disease.
- There was insufficient evidence to suggest a meaningful clinical difference between the drug and other biologic drugs for the treatment of Crohn’s disease.
- The Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the manufacturer which were able to address the concerns identified by the CDEC with respect to the cost-effectiveness and value for money.

Other Information

None
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 (DBC) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the Common Drug Review (CDR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit the The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.