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>glatiramer acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Glatect™</td>
</tr>
<tr>
<td>Dosage Form(s)</td>
<td>20 mg/ml</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Pendopharm, Division of Pharmascience Inc.</td>
</tr>
<tr>
<td>Submission Type</td>
<td>New Submission</td>
</tr>
<tr>
<td>Use Reviewed</td>
<td>Relapsing Remitting Multiple Sclerosis (RRMS)</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/node/88649">www.cadth.ca/node/88649</a>.</td>
</tr>
<tr>
<td>Provincial Review</td>
<td>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 CDEC recommendation and an internal review only. The DBC screened Glatect™ on March 7, 2017. The DBC advised that because glatiramer is similar to some of the other drugs used for the treatment of Relapsing Remitting Multiple Sclerosis the Ministry may accept the CDEC’s recommendation for glatiramer (Glatect).</td>
</tr>
</tbody>
</table>

Drug Coverage Decision

| Limited Coverage Benefit. Access the Glatect™ criteria from www.gov.bc.ca/pharmacarespecialauthority |
| Date | November 27, 2018 |

Reason(s)

Drug coverage decision is consistent with the CDEC recommendation.

- The drug was similar to the reference glatiramer (Copaxone) with respect to efficacy and safety.
- Based on economic considerations and the submitted product price, the drug was cost effective and offered value for money.
- As of November 27, 2018, all Special Authority (SA) requests and renewals for glatiramer acetate for multiple sclerosis patients will be approved for Glatect™ brand only. Patients with existing SA approval for glatiramer will have coverage for both brands during the transition period beginning November 27, 2018 until May 28, 2019, when Copaxone® coverage for MS patients ends.

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.