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>Brand Name</th>
<th>Dosage Form(s)</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>sofosbuvir-velpatasvir</td>
<td>Epclusa™</td>
<td>400 mg/100 mg tablet</td>
<td>Gilead</td>
</tr>
<tr>
<td>asunaprevir</td>
<td>Sunvepra™</td>
<td>100 mg capsule</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>daclatasvir</td>
<td>Daklinza™</td>
<td>30 mg and 60 mg tablets</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>elbasvir-grazoprevir</td>
<td>Zepatier®</td>
<td>50 mg/100 mg tablet</td>
<td>Merck</td>
</tr>
<tr>
<td>ombitasvir-paritaprevir-ritonavir</td>
<td>Technivie™</td>
<td>12.5 mg/75 mg/50 mg film-coated tablets</td>
<td>AbbVie</td>
</tr>
</tbody>
</table>

Drug Coverage Decision

Limited Coverage Benefit. Access the criteria from [www.gov.bc.ca/pharmacarespecialauthority](http://www.gov.bc.ca/pharmacarespecialauthority)

Submission Type

New Submission

Use Reviewed

Chronic Hepatitis C (CHC)

Common Drug Review (CDR)

Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions. Visit the CDR website for more details: [www.cadth.ca/node/88649](http://www.cadth.ca/node/88649).

Provincial Review

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. As the Ministry already provides coverage for some chronic hepatitis C medications similar to drugs under review, no DBC review was required.

Date

March 21, 2017

Reason(s)

- Epclusa, Sunvepra, Daklinza, Zepatier and Technivie were reviewed by the CDR and received recommendations to be reimburse with criteria and conditions, including price reductions.
- Clinical data supports use of these medications for the treatment of CHC.
- BC participated in and co-led with Ontario the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with Gilead, Bristol-Myers Squibb, Merck and AbbVie to improve accessibility to CHC treatments and ensure financial affordability and sustainability.
- pCPA negotiations concluded successfully with agreements reached with three drug manufacturers, Gilead, Bristol-Myers Squibb, and Merck.
- Effective March 21, 2017, PharmaCare covers treatment-naive or treatment-experienced adults with chronic hepatitis C (CHC) genotype 1, 2, 3, 4, 5 or 6 who have liver fibrosis stage:
  - F2 or greater (Metavir scale or equivalent) including decompensated cirrhosis, or
  - lower than F2 AND meet one or more of the following criteria:
    - Co-infection with HIV or hepatitis B virus
    - Post-organ transplant (liver and/or non-liver organ transplant)
    - Extra-hepatic manifestations
Chronic kidney disease stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease Outcomes Quality Initiative
- Co-existent liver disease with diagnosis evidence for fatty liver disease (e.g., non-alcoholic steatohepatitis)
- Diabetes for which patient is receiving anti-diabetic drugs
- Women who are planning to become pregnant within the next 12 months
  - Coverage criteria for sofosbuvir (Sovaldi®) and ledipasvir-sofosbuvir (Harvoni®) is also modified to reflect access for expanded patient population.
  - As an agreement was not reached with AbbVie, Technivie is not an eligible PharmaCare benefit and effective March 23, 2017, PharmaCare will no longer approve new requests for coverage of ombitasvir/paritaprevir/ritonavir and dasabuvir (Holkira® PAK). For patients whose coverage of this drug was approved before March 23, 2017, PharmaCare will continue coverage until their current Special Authority expires.

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.