

# Drug Coverage Decision for B.C. PharmaCare

## 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

|                               |  |
|-------------------------------|--|
| <b>Drug</b>                   | <b>simeprevir</b>  |
| Brand Name                    | Galexos™   |
| Dosage Form(s)                | 150 mg oral capsule  |
| Manufacturer                  | Janssen Inc.   |
| <b>Submission Review</b>      | <b>New Submission</b>  |
| Use Reviewed                  | For the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin (PR), in adults with compensated liver disease, including cirrhosis, who are treatment-naïve or who have failed previous interferon therapy (pegylated or non-pegylated) with ribavirin.   |
| Common Drug Review (CDR)      | Yes.<br><a href="http://www.cadth.ca/media/cdr/complete/SR0347_complete_Galexos-Jun-20-14.pdf">http://www.cadth.ca/media/cdr/complete/SR0347_complete_Galexos-Jun-20-14.pdf</a>  |
| Drug Benefit Council (DBC)    | DBC met on September 15, 2014 to reaffirm CDEC's recommendation. They were provided with various inputs including: final review completed by the Common Drug Review (CDR) in June 2014, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC). The DBC also were provided with Patient Input Questionnaire responses from 8 patient and 1 patient group; Clinical Practice Reviews on simeprevir from 2 specialists; Clinical Practice Reviews on simeprevir for the CHC genotype 1 infection treatment of co-infected human immunodeficiency virus (HIV) from 5 specialists; Manufacturer comments to the CDEC recommendation and reasons; an abstract of ongoing trial, study C212, investigating the efficacy and safety of simeprevir for the CHC genotype 1 infection treatment of co-infected HIV patients; as well as a Budget Impact Assessment. |
| <b>Drug Coverage Decision</b> | <b>Limited coverage benefit.</b><br><a href="http://www.health.gov.bc.ca/pharmacare/sa/criteria/restricted/simeprevir.html">http://www.health.gov.bc.ca/pharmacare/sa/criteria/restricted/simeprevir.html</a>  |
| Date                          | October 28, 2014   |
| Reason(s)                     | <b>Drug coverage decision is generally consistent with the CDEC recommendation and reaffirmed by DBC.</b> <ul style="list-style-type: none"> <li>Based on the available clinical evidence, more patients treated with simeprevir plus PR had sustained virologic response (SVR), which is a measure of successful treatment of CHC, compared to patients treated with PR alone.</li> </ul>   |

|                   |   |
|-------------------|---|
|                   | <ul style="list-style-type: none"> <li>• The DBC also reviewed the preliminary results of Study C212 and determined that the SVR results and safety of simeprevir plus PR for the co-infected HIV patients were similar to the studies that did not include patients co-infected with HIV..</li> <li>• Due to insufficient evidence comparing simeprevir with the other available protease inhibitors, telaprevir or boceprevir, CDEC recommended that the cost for a course of therapy with simeprevir should not exceed the cost of other currently available direct acting antivirals (DAAs).</li> </ul> |
| 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](#) 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

For more information about the B.C. Drug Review Process, please visit <http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc2.pdf>.

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