Welcome to BC PharmaCare's Public Input Questionnaire for drugs being reviewed under the B.C. Drug Review Process.

This questionnaire is for [simeprevir].

Patient Groups have to register before completing the questionnaire. Not sure your group is registered? Check our list of registered groups.

Your group can complete this patient group questionnaire only once. If you submit multiple questionnaires, only your last submission will be sent to the Drug Benefit Council for consideration.

To protect the privacy of members in your group, please do not include in your response names of individuals or companies, locations, or any other information that might identify them or anyone else.

Completing the questionnaire

Mandatory questions are flagged with a red asterisk (*).

If you decide not to provide the required information, click the CANCEL button at the bottom of this page to exit the questionnaire. To protect your privacy, your browser window will close.

You do not need to answer all the optional questions. You need only answer those that you think apply to patients in your group.

To protect your privacy, please close this browser window after you complete this questionnaire.

Respondent information

To have your input accepted, you must complete the Confirmation of Eligibility, Contact Information and Conflict of Interest Declaration sections of this questionnaire.

Confirmation of eligibility

1. I am a resident of British Columbia, **AND**

I am an authorized member of a Patient Group that represents B.C. patients who have the condition or disease for which this drug is used.*

X

Yes

No

Contact Information

Your organization's contact information will only be used to retrieve your submission if you submit a request under the Freedom of Information and Protection of Privacy Act (FOIPPA). It will not be used for any other purpose.

Your organization's name, however, will be included as part of your submission to the Drug Benefit Council.

2. **Patient Group Name and name of representative completing this questionnaire***

HepCBC Hepatitis C Education and Prevention Society, representative completing questionnaire:REDACTED

3. **Organization's Address** *

PO Box 46009, 2642 Quadra Street, Victoria, BC

4. **Postal Code** *

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Conflict of Interest Declaration

To make sure the Drug Review process is objective and credible, everyone who provides input has to tell us about any possible conflict of interest.

A conflict of interest exists if you, an immediate family member or your organization might benefit from the outcome of the review. For example, if you or your family own stock in the company that makes the drug, there could be a financial benefit IF PharmaCare decides to cover the drug. If your organization receives funding from the drug company, there could be a financial benefit (such as ongoing or increased funding) IF PharmaCare decides to cover the drug.

Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry (e.g., educational or research grants, honoraria, gifts and

salary) as well as affiliations or commercial relationships with drug manufacturers or other interest groups.

Even if you or an immediate family member, or your organization, has a conflict of

interest, your input will still be considered as long as you declare the conflict of interest in your answers to the questions. All information you provide is protected under the Freedom of Information and Protection of Privacy Act.

5. Do you have any Conflict(s) of Interest to declare?
*(If you answer "yes," please complete Question 6 below.)**

X◉ Yes

○ No

6. Describe any Conflict(s) of Interest below.
(Complete this question only if you answered "yes" to the previous question)

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last three years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boerhinger-Ingelheim, and AbbVie. In addition, the author of this report has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

Questions on drug under review

Question 7 is mandatory; all other questions in this section are optional.

7. Have you read the PharmaCare information sheet for this drug?*

If you would like to read this information now, click on the "this drug's information sheet" link in the *What this drug is for* column of the List of Drugs Under Review. The information sheet will open in a new window.

*

X◉ Yes, I have read the information sheet

○ No, I have not read the information sheet

8. Describe how the condition or disease for which this drug is used affects the day-to-day life of patients in your group.

Pt. 1: Symptoms of my HCV include brain fog, Fatigue, Vision and Dizziness. These symptoms can last for a day or for hours, come without warning and cripple my ability to work. From this comes further issues of embarrassment and anxiety having to tell my employer that I can't do my job as expected and the fear of revealing my secret of HCV. This is further compounded when I tell my family I can't work or enjoy the pleasures of life I'm used to, They don't see bandages or crutches and ponder what my illness is really is doing to me.

Pt. 2: My diagnosis with Hepatitis C eight months ago has been devastating. I received blood transfusions 34 years ago and though I have remained fairly healthy, I now live in constant fear that my advanced liver fibrosis is getting worse. I try to keep these thoughts at bay, I struggle every day to keep healthy and happy. Specific symptoms that I deal with are fatigue, joint inflammation and a compromised immune system.

Pt. 3: It makes me tired and confused. I have hepatitis-c mediated fibromyalgia.

Pt. 4: My symptoms such as insomnia, tiredness, itchiness, inability to tolerate prescription medicines, swelling of belly and constipation, fear of accidentally infecting someone else, make day to day life difficult. Also concern that not treating this disease is causing more liver damage.

Pt. 5: "I am lucky to have a wonderful husband. The cost of going through treatment financially fell a lot on him (over the counter meds and the loss of my productivity - I work from home) and of course it is difficult for a loved one as well as other family members to watch you go through such a challenging treatment. My husband lost a lot of sleep due to sleeping next to me while on treatment as I moved around a lot and had to get up in the middle of the night for meds. All that said, we are very fortunate that I was able to access treatment before I became ill from Hep C (I am currently undetectable but have to wait for 2 more months to see if it is permanent). If I had been seriously ill, I believe the impact on my husband and family would have been much greater."

The #1 problem mentioned was fear of losing our jobs, being debilitated, comatose, or dying prematurely, especially for those of us with family members who depend upon us.

Stigma was #2 problem mentioned by most patients:
"I have never injected myself, had a tattoo or had any additions, yet I am constantly fighting ignorance and assumptions from the regular public and health professionals. It sucks."

Stopping the spread of HCV:
"A person with HCV puts their family, doctors, dentist…everyone…in danger. Yes, there are universal precautions, but there are accidents, too."
"I was lucky not to pass it on to my family."

Whole body, not just liver:
"It can affect energy levels, joint pains, brain function, the immune system. It can attack the liver, kidneys and heart--all of the vital organs."

Fatigue, weakness, and lack of energy were mentioned by most. Some need to sleep 12 hours a day or more. When they wake up, they still lack energy or strength.

"I have too low energy level for most activities I'd like to be doing, but couldn't get out of chair sometimes."

Pain from liver and joints is terrible and debilitating.

Bone problems:
"I have osteopenia and I am no longer able to do anything requiring sustained energy or more complicated movements."

Nervous system and brain problems:
"Memory loss is so frustrating!"
" I have lost fine motor control. I have peripheral neuropathy due to the disease.
" I have experienced brain fog at times. Especially around recalling nouns (not all the time), it can be frustrating as I am a writer and like to be articulate!"

Hormonal problems:
“I believe it led to breast cancer, since the liver regulates hormones.” I was lucky to not pass it on to my family.

“No more pub night!”

Impact on caregivers:
All patients commented on the financial impact on the entire family and the increased responsibility and stress all family members went through. Plus there was the emotional impact of not knowing if the treatment was going to work, coupled with the patient’s terrible moods, particularly irritability or depression.

9. If the patients in your group have tried the drug under review, please tell us about the effects they experienced.

   Pt. 1: I have not tried simeprevir/GALEXOS but have spoke with others who have used it, are now cured with few or little side effects.

   Pt. 2: I have read many reports of the successful out come of treatment on varied genotypes using simeprevir/GALEXOS.

10. What drugs or other treatments have the patients in your group used, or are currently using, for

the condition or disease for which this drug is used?

Please list all of the drugs and tell us about the experience of the patients in your group with each treatment.

Genotype 1 patients are being treated either with the current Standard of Care (triple therapy with Interferon, Ribavirin, and either boceprevir or telaprevir OR many of them are on clinical trials since we all liver very close to a research clinic (Percuro) in Victoria, BC. Genotypes 2 and 3 patients are same as above, except of course the current SOC does not include boceprevir or telaprevir. We do not have any other genotypes other than 1-3 represented.

In addition, one of our Genotype 3 patients who has now failed treatment twice (including one recent clinical trial) is taking a Chinese therapy which is keeping him in good condition while he awaits some new and more effective Western cure. Those cured are still left with liver damage that can leave them at risk for liver cancer and failure for many years following the end of treatment. Early treatment is vastly more critical than many doctors assume.

Pt. 1: I have used Pegetron interferon and ribavirin. The side effects were unbearable, for 6 months I was unable to work, alienated from my family and mostly bed ridden for the entire 26 weeks. This was the worst experience of my entire life and would not wish it on anyone. Six months post treatment HCV returned. I doubt I would take treatment again if offered even though this will mean death for me.

Pt. 2: I have been on trials with interferon and have nothing good to say about it. My hope is that Galexos will be used in interferon-free combinations soon. I was almost cured in an interferon-free trial with Merck drugs but it triggered strong atrial fibrillation (pre-existing).

Pt. 3: “I was in a horrible mood when I was taking interferon treatment. I did not take antidepressants. The treatment may well have played a part in the demise of my marriage. Personally, I probably could have survived without support, but it would have been very difficult. As it was, I had help shopping, preparing food, doing housework, driving. But I was willing to do anything to get rid of the virus.”

Pt. 4: Have not yet tried treatment due to side-effects, rigidity of pill dose schedule, as well as length of treatment time. Also have been waiting for new drugs which provide better cure results, and therefore will hopefully only have to do this once.

Pt. 5: I just completed 28 weeks of triple therapy using Interferon, Ribavirin, and Victrelis. The side effects were numerous and I experienced most of them. My HG dropped significantly, down into the mid 80's for the last weeks and weeks following tx. My white blood cells were diminished significantly. To list just a few of the sides which came and went: nausea, runs, headaches, dry mouth, nose, eyes, hair loss, vision changes, tinnitus, sinus irritation, bleeding and infections, bad rash, horrible taste in mouth, significant brain fog, fatigue, joint and muscle pain, pain around the liver, difficulty on inclines, asthma symptoms intensified, restless legs in evening, increased acid reflux, sore mouth and gums, heightened senses including: hearing, taste and skin. Diminished ability to smell... I could go on but these are all par for the course.”

Pt. 6: Worst side-effects with triple-therapy (Victrelis): RASH, then bad taste, need to eat when feeling ill, dry mouth especially at night, sinus irritation, weakness caused by low HG, and difficulty sleeping due to: skin irritation, joint pains, acid reflux and having to get up for meds.

Pt. 7: Cirrhotic woman now on triple therapy says: “Not as bad as previous therapy, weak & tired, zone out, shaking & trembling, liver pain, coughing up blood clots “

Pt. 8: When I was on the three combo drug therapy, I developed 'firehea' from the telaprevir. This is something that only someone on this therapy can understand. It is an unbearable burning sensation when you go to the bathroom.

Pt. 9: Boceprivir can make everything taste REALLY BAD. It's like sucking on a rubber tire and not being able to spit it out.

Pt. 10: "Hopefully, I will remain undetectable. If not, I would prefer to be on a medication that I could take 1x a day than the Victrelis that I had to take 3 times a day. Sleep would be better if not broken up by alarms for medication. That would be a huge step forward! And yes, for those who have to work to support themselves or family through treatment, not having to get up at night for meds would make a huge difference."

11. Please tell us why your organization believes this drug should be included in the BC PharmaCare program.

1. **Fewer side-effects** than boceprevir/VICTRELIS™ or telaprevir/INCIVEK™.
2. **Lower pill burden** than boceprevir or telaprevir (simeprevir is given once a day).
3. **Fewer dietary requirements** than telaprevir, though patients still must take simeprevir with food.
4. Even after stronger, more expensive, drugs such as sofosbuvir/SOVALDI™ are approved (we assume this will happen sometime this year), they may not be the first choice. BC Pharmacare has said they "may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition." For genotype 1 patients, this could possibly mean **they'd have to go through Triple Therapy first, and fail it before BC PharmaCare would cover the more effective but costlier drugs**. In this case, the addition of simeprevir to the PharmaCare formulary looks particularly attractive, providing all patients – not just the wealthy or those with third-party insurance accessing simeprevir now – with a less harsh alternative to boceprevir and telaprevir.
5. Simeprevir is already being **prescribed off-label, in combination with other drugs such as sofosbuvir**, with or without ribavirin, particularly for hard-to-treat patients such as those with advanced liver damage, prior null response to treatment, and genotype 1 and 4 patients who cannot take interferon. This combination is currently undergoing trials with all genotypes. Once both simeprevir and sofosbuvir are covered by PharmaCare, it is likely that combining them will be another excellent option for patients who do not respond to standard of care.
6. There is one problem with simeprevir, but Janssen seems to be dealing with it proactively. If a patient has the genotype 1a form of the virus, they must take a blood test to find out if their virus has a "Q80K" mutation (see **May, 2014 hepc.bull** for more information). If it does, the patient should not take simeprevir as it is not effective in the presence of Q80K. **Janssen covers the cost of the Q80K test.**

Conclusion

Thank you for your organization's input to B.C. PharmaCare's review of this drug.

Once the survey period for this drug ends, we will send everyone's responses to the Drug Benefit Council for consideration when they make their drug coverage recommendations.

Before your input is forwarded to the Drug Benefit Council, we will remove all personal information, including the name(s) of patients and any other identifying details. The name of your organization, however, will be included as part of your submission.

Would you like to learn more about the drug review process? Visit the drug review process overview on the PharmaCare website.

Would you like to learn about the drug review decisions? Visit the PharmaCare drug coverage decision summaries on the PharmaCare website.

Click the DONE button to submit your input and close this questionnaire.

After you have clicked "DONE," your browser may ask you whether you want to close the questionnaire window. To protect your privacy, please answer "yes" at the "close this window?" prompt.