Template for Submitting Patient Group Input to the Common Drug Review at CADTH

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Simeprevir – for chronic hepatitis C
Name of patient group	HepCBC Hepatitis C Education & Prevention Society
Name of primary contact for this submission:	Removed for privacy reasons
Position or title with patient group	Board Member, and HCV+ Volunteer
Email	Removed for privacy reasons
Telephone number(s)	Removed for privacy reasons
Name of author (if different)	N/A
Patient group's contact information:	
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1.1 Submitting Organization

HepCBC is a non-profit society run by and for people infected and affected by hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. Our office with our only paid employee (an office mgr.) is in Victoria, BC. We also have activities and groups in Nanaimo, BC and Surrey, BC. Our representatives attend provincial and federal-level conferences and we give information and support world-wide through our website. We publish a monthly bulletin, the hepcbull. We focus on providing "clean and sober" peer support groups, anti-stigma activities, prevention education to young people, and encourage testing among at-risk groups -- including those who are no longer at risk but may have contracted hepatitis C decades ago. We work alongside local HIV/AIDS organizations in support of co-infected people.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

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.

One of the patients who made a submission received Victrelis on a compassionate basis from Merck Canada, but has no other affiliation with them.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

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.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

This report was developed using data obtained from answers submitted by patients through our website and from a group interview during a regular patient peer support group meeting. In total there were submissions by eight patients, of which these are the characteristics:

1 - 55, F – Cirrhotic, failed treatment four times, now participating in a trial (genotype 1A)
2 - 63, M - Successfully cured in trial 2 years ago
3 - 56, M - Failed treatment twice (genotype 3)

4 - 57, M - Cured after transplant followed by 72 weeks treatment (genotype 1A)
5 - 65, F - Failed treatment once, successfully cured in trial 8 months ago (genotype 1B)
6 - 67, F - Failed treatment five times, successfully cured in trial 7 months ago (genotype 1B)
7 - 64, F - Failed treatment once, successfully completed new SOC treatment several weeks ago, awaiting news of SVR
8 - 64, M - Failed treatment twice, now awaiting start of trial (genotype 1A)

In addition, two of the people submitting are volunteers who have manned a hepatitis C patient phone support line for several years, and have broad knowledge of patient concerns and experiences.

2.2 Impact of Condition on Patients

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!”

2.3 Patients’ Experiences With Current Therapy

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.

The current therapy has cured many but not all of us. The current SOC triple therapy is more effective than previous SOC for Genotype 1 patients. However, of course, 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.

ADVERSE EFFECTS:
"I just completed 28 weeks of triple therapy using 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."

"I have recently responded (SVR) to a clinical trial with Asunaprevir/Daclatasvir which was interferon-free and ribavirin-free. Current approved therapy (pegIFN/RBV/pi) was not appropriate for me. I was IL28b TT allele, and experienced breakthrough with pegIFN/RBV, plus it affected my eyes. My latest clinical trial produced NO side-effects.

HARDEST ADVERSE EFFECTS:
"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.

The side effects I found most difficult with pegIFN/RBV were the loss of energy, loss of coordination, some pain, and the neutrophil drop, making me susceptible to infections, to say nothing of the hair loss. And I was among those who were less affected by treatment. I was able to continue working. Frankly, I welcomed the weight loss."

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"

ACCESSIBILITY:
"Had Merck Canada not given me the Victrellis on a compassionate basis and my husband's extended medical covered dual therapy, I would have had to wait as I did not qualify for coverage under BC Meds guidelines."

"Had I taken current therapy (instead of the non-Interferon, non-Ribavirin Asunaprevir/Daclatasvir trial), I would have had a substantial initial cost each year. During my previous treatments, it was difficult to assess whether or not the pharmacy had actually kept the IFN refrigerated. Sometimes my medicine did not arrive at the pharmacy on time."

Cirrhotic woman on triple therapy: “Financial hardships accessing therapy, finally got help from manufacturer & Pharmacare because deductible was high”

NEEDS NOT COVERED:
” 1) Financial loss due to:
A) loss of productivity on treatment
B) over the counter side effect medication (you can spend a fortune on creams when you have a bad rash!!!)
2) Clear directives for primary physicians. Example: I find myself educating them, my family doctor of over 10 years just left but he never once suggested a liver ultrasound, I had to ask for one after reading about its necessity online! My new doctor isn't aware that people who had Rhogam (a blood product) before 1992 are at risk for infection and my Chiropractor asked if you can get it from Ice cubes after watching a commercial.”

“I have resolved my infection, thankfully. Current standard treatment would not have worked with me, and would have further damaged my eyesight.”

ALTERNATIVE THERAPY:
Genotype 3 male who failed treatment and is now on Chinese therapy awaiting new treatments says this therapy is “Subtely controlling the rashes, makes me feel better, no adverse effects. It is a financial hardship, though: $900 for 4 months! And admittedly it is not a cure”

2.4 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.

“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.”

“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.”

“They get yelled at a lot, adds a lot of stress & pressure, impacts their work schedule.”

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

SAME AS IN SECTION 2.1

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had to Date With the New Drug?

The general consensus was that simeprevir will be a welcome but minor improvement in terms of ease of use and possibly decreased side-effects, but lacking really compelling factors unless it provides increased efficacy or applicability to a broader range of genotypes.Patients really stress they want interferon-free, and even ribavirin-free treatments since they have such terrible side-effects. Adding simeprevir to them won't be a great advancement.

The obvious benefits of this drug over others currently available would be the facts they would only have to take one pill instead of many, they wouldn't have to get up at night to take a pill, and they wouldn't have to take the specialized food with the pill. However the most important thing was stated clearly by this patient:
"We'd do anything for a cure. Absolutely. We've been through so much already including dark, scary moods, etc."

"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."

"I hope I never have to take simeprevir, since I am now undetectable, but if I should relapse, I would want something else available. Current therapy doesn't "cure" everyone, producing a serious gap. We need medications that will produce responders in all patients. This doesn't just affect those of us who have been infected. We need to stop the spread of the disease. As far as side effects go, I wouldn't take a drug that would affect my vital organs or eyesight adversely. The ability to live independently and enjoy life relatively free of pain, without draining the medical system or becoming addicted to any drug would be adequate benefits for me."

b) N/A – we did not have any patients who had been in a trial with simeprevir.

Section 4 — Additional Information

"I am thankful that you are reaching out to find out what patients think. I just hope that the other patients will answer. Many will not have access to the questionnaire. And many will not be able to answer it anymore, due to hepatic encephalopathy."

"We need more drugs, and they should be paid for, and available to anyone – including prisons, for free, & cover all genotypes."

"In particular, more research for Genotype 3 is urgently recommended."