Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		**Ombitasvir / paritaprevir / ritonavir and dasabuvir**
Name of the patient group		HepCBC Hepatitis C Education and Prevention Society
Name of the primary contact for this submission:		REDACTED
Position or title with patient group		Board Member and HCV+ Volunteer
Email		REDACTED
Telephone number(s)		REDACTED
Name of author (if different)		
Patient group's contact information:	Email	info@hepcbc.ca
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	Website	www.hepcbc.ca
Permission is granted to post this submission		X Yes ☐ No

CADTH will post this patient input submission on its website if permission is granted. See CDR Update — Issue 99 for details.

1.1 Submitting Organization

HepCBC is a registered non-profit society run by and for people infected with, or affected by, hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. Our only office is in Victoria, BC. Run primarily by volunteers living with HCV since 1996, we have activities and groups in Nanaimo, Vancouver, and Surrey, BC, and travel throughout the province doing outreach. 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 *hepc.bull*. We provide peer support groups, anti-stigma activities and prevention education to the general public, and general hepatitis information especially to baby-boomer, aboriginal and immigrant communities. We 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 four years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences,

Janssen Pharmaceuticals, Bristol Myers Squibb, Boerhinger-Ingelheim, and AbbVie.

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 and two of those who contributed individual patient submissions have 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 from:

(1) A patient survey advertised through our website and our email list. In total there were submissions by twelve people living with hepatitis C (5 male, 7 female, with mean age 59 yrs, range 35 – 68 yrs,) Genotypes 1 through 4, and all ranges of liver damage (F0 through advanced cirrhosis) were represented. Eleven were from British Columbia and one was from Manitoba. One submitter had gone through a trial of this AbbVie therapy.

(2) In addition, three of the above are volunteers who have actively manned HCV+ phone and email support systems or several years, and have broad knowledge of patient concerns and experiences.

(3) We've included aggregate input from one of our monthly support groups as well.

2.2 Impact of Condition on Patients

In the last few years HepCBC has done 11 hepatitis C drug submissions for both CADTH and BC PharmaCare, and have answered Questions 2.2, 2.3, and 2.4 as many times. Our respondents are, quite frankly, getting tired of answering the same questions so many times. And as a patient group, so are we. To avoid re-inventing the wheel we are shortening our responses and suggest you review our more detailed answers in these three recent submissions, made in July, August, and October of this year:

http://hepcbc.ca/wp-content/uploads/2014/10/20141008_ledipasvir_sofosbuvir_HARVONI_CADTH_redact.pdf

http://hepcbc.ca/wp-content/uploads/2014/10/20140826_HCV_GT1_TherapeuticReview_CADTH.pdf

http://hepcbc.ca/wp-content/uploads/2014/10/20140711_sofosbuvir_SOVALDI_Pharmacare_redact.pdf

What we are struck by at this particular time, both from the individual submissions we received and from what we are hearing on a daily basis from our clients, most of whom are in the "baby-boomer" cohort, is a growing sense of desperation and despair. They are like drowning men who can see the

shore, but they're swimming against the tide, and the harder they swim, the further the shore seems to be receding into the distance. They know life-saving drugs are out there if they can just hold on long enough, to keep the liver cancer and end-stage-liver-disease at bay until the drugs are covered by their provincial drug plans. They know their time is almost over -- unless they can get treated in time. They are depressed, angry, and yet - sometimes - hopeful.

The debilitating stigma is still there, but it seems HCV+ baby-boomers are generally becoming more willing to be open about their status. The promise of the new drugs has meant hepatitis C has been covered more often in the media, and the public is starting to hear the voices and see photos of people fighting the disease who are clearly not IV drug users; stereotypes which fed the stigma are being questioned. This makes it easier for people to 'come out of the closet' and seek testing and treatment. Patients and their families are at the end of their ropes, ready to do whatever it takes to get onto treatment, even if that involves exposing themselves to possible stigma at work, or amongst friends and family. Samples of their voices follow:

(F, 56, with cirrhosis, treatment-experienced and unable to take interferon): "I am so tired and weak. I feel like I am running out of time and I am frantically trying to build my legacy, but I am so tired and at times cannot think at all. It feels like there is a brick inside of my head and I am not quite here, or anywhere for that matter. I desperately need treatment but the system takes so long. My liver is badly scarred and I know it is a slowly-progressing disease, but how long can I go on feeling like I am half dead, and sad because it is too much effort to go anywhere or do anything. I do not have energy to look after myself properly, so often my husband helps. He goes to karaoke alone now because I am too sick. I cry because I do not want my life to end this way. That is how my life is right now. If I don't get treatment soon I am not going to be here for much longer."

(F, 66, recently cured through a trial): "Some of my friends are starting to develop ascites and esophageal varices, symptoms of advanced cirrhosis or even end-stage liver disease. They have heard that the new drugs probably won't be available to people with such advanced disease, so they are keeping their symptoms to themselves. They don't want these diagnoses to go onto their medical record for fear it will prevent them from eventually getting cured. This is risky; without treatment such as paracentesis or esophageal banding, they could die."

At the same time a high percentage of HCV+ people are asymptomatic while the disease does its terrible damage to their bodies. Many of them do not even know they have the disease until they receive the terrible news that they have liver cancer, or need a transplant. These people need to be tested, found, and treated as soon as possible. They are in as much danger of morbidity and mortality as those who are symptomatic.

2.3 Patients' Experiences With Current Therapy

See links in Section 2.1. Through the Internet and support groups, patients are very knowledgeable about the side-effects of interferon, ribavirin, telaprevir, and boceprevir. While recognizing and appreciating their merits, they want to avoid all of these drugs as much as possible. While simeprevir is now publicly funded in BC and patients know it has fewer side-effects than the other protease inhibitors, few patients are taking it simply because it is still paired with interferon and ribavirin.

The concept "current therapy" has become far more diversified over the last year, with patients getting treated quite differently according to genotype, their stage of liver disease, and whether they have private insurance or not. A large percentage of patients we come in contact with are being "warehoused", either by doctors or by themselves, simply rejecting the idea of taking current therapies, knowing vastly superior drugs are so close to being approved. Some of their voices:

(M, 58): "I was treatment naïve and was very concerned about the treatments available because I had talked to a few people about the types of drugs provided and had been on the internet reviewing my options. The standard treatment at the time was a combination of interferon and Ribavirin with a success rate of 40% and later with the addition of either boceprevir or telaprevir that was increased to 50-70%. The combo of interferon and either boceprevir or telaprevir was very hard on them and complications range from sickness to extreme rashes and for lack of a better term I will call it fire butt. My (worst) concern was what I had read about the lasting effects of the interferon. So I stalled until I became very ill and there was no more waiting."

(M, 60):"15 years ago, my wife went on interferon+ribavirin treatment and is now Hep C free. She is still trying to recover from the side effects from this treatment. There is no follow up for her, the doctors don't know enough and don't care about the side effects you are left with after the treatment. She went through hell while on this drug."

(F, 67): "I had treatment with the SOC drugs almost 4 years ago but had to stop after 7 weeks because the interferon was damaging my eyesight. I am not on any current treatments because of the interferon that is included in them. I use herbs to help with my management of Hep C."

(F, 56): "I am treatment experienced, interferon/ribavirin, 2008 – 2009. SVR at 3rd month during treatment. I relapsed one month following treatment. Side effects were mainly anemia. I am (still) awaiting affordable treatment."

(F, 67): I am treatment-experienced, with interferon + ribavirin, 2010-2011. The treatment almost killed me and it didn't work. Later I was cured with an interferon-free, ribavirin-free BMS trial."

(M, 65): "My only experience with "current therapy" was with a Merck interferon-free trial, but it did include ribavirin. I had a major episode of atrial fibrillation during the trial and I was taken off the trial. I am now hoping to get treated with a medication which does not interfere with my heart medications."

2.4 Impact on Caregivers

See links in Section 2.1. The main impacts we see on caregivers are poverty, a sense of isolation, and uncertainty about the future. Poverty is due to their untreated HCV+ partner's/parent's/child's inability to lend support to the family, followed by the increased medical expenses as their condition

deteriorates. Caregivers often feel isolated due to stigma against those with hepatitis C and ignorance about how it is spread. They also spend much of their time looking after their HCV+ family member, or doing the chores the family member no longer can do, which cuts down on the time they used to have to socialize. There is little way to plan for a future when you don't know how long your partner will be able to live independently, or to live at all; uncertain if your partner will be able to benefit from the new HCV drugs, or if he or she will develop liver cancer or need a liver transplant before they are accessible. Some voices:

(M, 60): "My wife is now my caregiver, trying to keep me on a balanced diet to keep my liver from failing with no money for proper food."

(M, 65): "The new therapies are so gentle compared to interferon-containing regimes. I do not see AbbVie's 3D as having any impact on caregivers at all (during the patient's time of treatment)."

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Same as previous Section 2.1

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

a) Based on no experience using the drug:

Patients tend not to differentiate the various new drugs from one another since they're all so much better than the existing ones, and share the characteristics of being mostly tested on genotype 1, far greater efficacy, a far shorter treatment time, no interferon or needles, very few side-effects, and an extremely high price-tag. They really like the fact AbbVie's 3D will give some competition to Gilead's Harvoni, anticipating that the price of a cure will go down. The downside is that the AbbVie drugs often involve ribavirin, and that they consist of four pills a day rather than one. The number of pills per day is of little consequence; the ribavirin is more problematic though the shorter treatment time means that the side-effects will not be as serious over time. Patient advocates are very excited at the prospect of actually being able to eradicate the disease entirely from the world, though the price will have to be greatly reduced. Patient voices:

(F, 67): "After being cured, a person could lead a relatively "normal" life again. The positive side would be freedom from the damage the virus does to the liver and a possibility of the liver regenerating itself in 8 years or so."

(M, 65): "I have no direct experience of the drugs being reviewed; however, I do work in hepatitis C patient education and everything I have read is really exciting and promising. I would really like to see the AbbVie combo approved as soon as possible and hopefully covered very quickly by provincial Pharmacare plans. I am hoping that the 3D will help those who are interferon intolerant and who thus cannot take the Sovaldi and Galexos combos. As well, this will be so much better than the horrors of telaprevir. I would be willing to take the AbbVie combo at the drop of a hat. I really think it will cure me and that I won't have any side effects at all."

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Only one respondent had direct experience with AbbVie's 3D therapy, and he was extremely enthusiastic about it even though he had to take ribavirin with it. 100% of the people he knew on this trial achieved SVR.

(M, 58): "I had cirrhosis (Fibroscan 35 kPa), and was in an AbbVie 3D clinical trial called Turquoise II with ribavirin. I took these drugs for 24 weeks and there was shortness of breath. The ribavirin make it hard to sleep and focus at times, but other than that the trial was a piece of cake. I did not experience any of these (side-effects) from the AbbVie drugs, but the ribavirin does make you anxious at time right after taking it and sleep was a problem at times. I understand that ribavirin may not be used for most treatments. So without that, the patient will have an easy time on this combination. What people need to look at is the proven success rate of this combo versus the average success rate of the old treatment, and then factor in the lasting damage the interferon can have on your system, and using the AbbVie drug is a no brainer."

"A lot of people who have done the old treatment have had to repeat it, at great risk to their health and a huge cost to the medical system. In contrast, this (AbbVie) treatment cures almost everyone. In the trial I was in there was ZERO relapses. I have been free of the virus since November, 2013 and my last Fibro Scan reading has now dropped from 35 down to 20 kPa." (His cirrhosis has reversed and is almost gone; the beginning of cirrhosis is approximately 17 kPa).

Section 4 — Additional Information

(F, 67): "Patients are really concerned that the prices of these drugs will be so high that CADTH (and/or provincial pharmacare plans) will either not approve the treatment at all, or will make treatment qualification criteria very high, or will decide that treatment-naïve people should first take and subsequently fail the current standard of care (with both interferon and ribavirin) before they're allowed to take AbbVie 3D therapy. There are no other diseases in which a patient has to prove significant damage to his/her bodily organs in order to get treated. And there are no others in which a patient has to take such clearly inferior - even harmful – treatments simply because of price."

(M, 58): "If you want to help Canadian citizens get rid of Hep C for good, the choice is easy. I am reading stories daily now with people on the new treatments clearing themselves of this disease. But I also hear the cries from those that are waiting to get cured; some are in the position that I was in and may not have long to wait, but either can't get access to the drugs or can't afford the cost. If I explained to you how lucky I feel and how much my health has returned would that convince you to make the right decision? I am counting on you to do the right thing and help these people out because they need and deserve your help."

(F, 35): "While I understand why treatment for genotype 1 is most important in North America, those of us with genotypes 2, 3, 4, and 6 are dying, too, and hope that once a treatment gets approved for genotype 1 that any additional applications for that drug to cover additional genotypes will get fast-tracked."

(M, 60): "Why do years of research on a drug to cure a disease that the average worker can't afford?"