Section 1 — General Information

<table>
<thead>
<tr>
<th>Name of the drug CADTH is reviewing and indication(s) of interest</th>
<th>Ombitasvir / paritaprevir / ritonavir and dasabuvir</th>
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<tbody>
<tr>
<td>Name of the patient group</td>
<td>Pacific Hepatitis C Network</td>
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<tr>
<td>Patient group’s contact information: Email</td>
<td><a href="mailto:info@pacifichepc.org">info@pacifichepc.org</a></td>
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<td>Website</td>
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<td><a href="http://www.pacifichepc.org">www.pacifichepc.org</a></td>
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1.1 Submitting Organization
Pacific Hepatitis C Network’s mission is to provide a means for sharing information and coordinating mutual support and action that will strengthen the capacity of individuals and organizations throughout British Columbia to prevent new HCV infections and to improve the health and treatment outcomes of people already living with HCV. Our members include people living with chronic hepatitis C, people who are HCV antibody positive, people at-risk for hepatitis C infection, and anyone interested or concerned about hepatitis C (service providers, health care providers, family, friends).

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering
Information was gathered through an online survey that was made available from November 11th to December 15th, 2014.

2.2 Impact of Condition on Patients
Hepatitis C (HCV) is a serious and potentially life-threatening liver disease that may lead to liver fibrosis, cirrhosis, cancer, liver failure, and even death. However, in many cases those life-threatening HCV developments are only fought after years of worrying over the future and dealing with other HCV symptoms, which may not lead to hospital stays or liver transplants, but, in their own ways, are far more debilitating.

Hepatitis C symptoms are numerous and affect patients differently. Symptoms, reported by our members, range from “have not had hep C symptoms” to being “seriously affected by nausea, vertigo, brain fog, itchy skin (especially thighs), arthritic knees and fingers and other HCV-related symptoms”. Furthermore, when asked if their HCV symptoms affected their daily living, someone replied: “I eat well and run and exercise and usually try to ignore the pain/discomfort.”

Another wrote: “I think I should have more energy than I do. I work at home as a freelance writer. My output seems to be declining, partly because of cognitive decline, difficulty remaining focused, holding it all in my head, etc. And I find myself unable to manage much beyond my writing (in terms of socializing or home/garden projects).”

What the person may be experiencing is “brain fog”, a common symptom of hep C. The experience of “brain fog” includes difficulty thinking, remembering, understanding, and focusing. “Brain fog” can be very disabling, impacting negatively on a person’s ability to function at home and in the workplace.
People with “brain fog” describe having to take manual jobs requiring less cognitive function, even though this can pose other challenges if that work requires physical labour of any kind as fatigue is sometimes also a symptom of hepatitis C. Comments received about how HCV impacts quality of life were: “It all depends on the amount of fatigue I feel, if bad it is a stay at home day and I was at one time a active person”, as well as, “work - i am too tired for the physical demands of my work”, and “I am extremely exhausted most of the time.”

The above quote not only touches on “brain fog”, but it also expresses the uncertainty, helplessness, and worry, that often surrounds hep C. HCV doesn't only take a physical toll on patients, but takes psychological and emotional tolls on patients and their support networks as well. This is due, in part, to that fact that it is a disease that one often needs to wait and get sicker before receiving treatment, but it is also a disease that people die of before being able to find a treatment able to cure their hep C. One member wrote: “To be rid of something that has the potential to destroy one’s body would have profound physical and psychological benefits.”

Lastly, these physical and psychological tolls are often worsened by the social isolation, which comes from suffering fatigue, other hep C symptoms, and from the stigma that comes as a result of having hepatitis C, a communicable disease. We know that those who are socially isolated have poorer health outcomes, do not access care as quickly or as often as they could, and can have more hospitalizations due to acute illness.

### 2.3 Patients’ Experiences With Current Therapy

The current standard of care is pegylated interferon with ribavirin alone or with either telaprevir or boceprevir (for HCV G1). Patients’ experiences with this treatment range from being able to continue work while on treatment to experiencing such severe side effects that they virtually cannot function and need help with basic daily living and childcare. However, experiencing few or no side effects wasn't an experience described by anyone who completed our survey.

What was mainly described, by those who completed our survey, was a treatment that didn’t have very good success in 'curing' their hepatitis C and that included side effects which made it difficult to complete. One person commented that their “severe anemia had to be treated with several blood transfusions when drugs would have worked but they were too costly and not covered by PharmaCare”, and another said, “now I feel worse then before Treatment without success”. These are not uncommon experiences.

Additionally, some patients find the pill burden of taking multiple medications several times daily both physically and mentally challenging. Some treatments involve patients waking early, staying up late, or carrying medications and food with them (risking social stigma or embarrassing explanations), and cause anxiety around missing a dose. Organizing their daily schedule around medication times can be overwhelming.

### 2.4 Impact on Caregivers

The worry and concern over health and well-being that comes with not feeling in control of one’s health and future isn’t just felt by those living with HCV, but by their caregivers as well. All caregivers express concern about how hep C is impacting the health of their loved one and if they hadn’t yet had treatment, are concerned about what treatment will be like. One of the most difficult situations is when treatment has failed and their loved one is still ill, or if treatment isn’t an option.

Caregivers talked about the complexity of needing to stay both alert to possible very adverse reactions while not interfering or being “in the face” of their loved one on treatment.
Furthermore, treatment not only affects the lifestyles of the patients but the lifestyles of their loved ones as well. For example, suffering from treatment side effects decreases what one can do and increases the workloads, such as household chores and income earning, of others. Caregivers note a lack of social supports that are able to step in to support them while their loved one is on treatment. They also note that the increased workload can be very difficult and, at times, they end up feeling resentful of their partner and then guilty because they were mad at a sick person.

In addition to feeling resentful and overwhelmed, they also reported suffering from depression, lack of sleep, and additional stress, while their loved one was seeking treatment.

After treatment some caregivers said their lives returned to normal, especially after a successful treatment with fewer adverse effects, but not always. Sometimes their loved ones continue to experience fatigue and other post-treatment conditions that continue to impact their lives and their families.

**Section 3 — Information about the Drug Being Reviewed**

### 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:

There are a couple of expectations for ombitasvir / paritaprevir / ritonavir and dasabuvir, however, the expectation that is foremost is that the treatment’s higher sustained virologic responses (SVR), which have been reached in clinical trials, will translate into a better chance of a cure for patients and, thus, enable them to start their lives anew.

In response to being asked what their expectations for the new drug are, one of our members wrote: “In my case, my expectation is that it would stop the virus from replicating and the cirrhosis and fibrosis I have would not get worse, it would just stay as it is now, and I would hope that I would feel better and be able to return to work.”

Secondly, there is an expectation that ombitasvir / paritaprevir / ritonavir and dasabuvir will help address a large gap of unmet patient need. There's currently no HCV treatment available in Canada for null responders, relapsers, or those who have already undergone the current standard of care. Thus, there is an expectation that this treatment will help address that gap.

Thirdly, due to it's low toxicity and lack of significant drug interactions, it is expected that ombitasvir / paritaprevir / ritonavir and dasabuvir will open up treatment to patients who couldn’t tolerate previous therapies (due to HIV co-infection, autoimmune conditions, or other co-morbidities). We know that ombitasvir / paritaprevir / ritonavir and dasabuvir has also greatly improved treatment outcomes for those with compensated cirrhosis.

Fourthly, ombitasvir / paritaprevir / ritonavir and dasabuvir is also known to be a huge improvement over current treatments because it can be taken without interferon and, thus, treatment can be free of interferon's side effects. When asked what they hope ombitasvir / paritaprevir / ritonavir and dasabuvir can achieve, people say things like: “Avoid the Interferon-related side effects. That's really my primary concern, and the primary reason I have not sought treatment these last 19 years. If it could also give me a shorter treatment time and a greater chance of success - great!”

In addition, people also expect that “their fibrosis or cirrhosis will reverse. They won't be at such risk of liver failure, cancer, or transplant. Some will be able to return to work. Quality of life of everyone will improve.” Basically, people expect that ombitasvir / paritaprevir / ritonavir and dasabuvir, and other new drugs will, “cure Hepatitis C with little to no side effects”.  It's that simple.
Finally, while most people are willing to accept serious adverse effects for weeks if there’s a high probability of a cure, the expectation is that ombitasvir / paritaprevir / ritonavir and dasabuvir has far fewer adverse side effects than current and past treatments.

**Section 4 — Additional Information**

“We need a treatment ASAP that is affordable to people like me. At this moment, because of demographics mainly, my only option is the boceprevir / peginterferon / ribavirin mixture approved and covered by PharmaCare. I have lots of scarring on my liver and advanced Hepatitis C, so the side effects of the interferon / ribavirin will be much worse. But I will do it just to get rid of this evil disease that has stolen my life from me.”

There is a want to get better, to improve one’s health, and to participate in more than they can with hep C, but we are concerned that the current standard of care that’s covered by PharmaCare, comes with side effects that not all can endure. We are concerned that treatments, such as ombitasvir / paritaprevir / ritonavir and dasabuvir, with less side effects and shorter treatment durations, will remain unaffordable and unreachable.

We are concerned as well that patients may have to first undergo and fail a very challenging, longer treatment with a lower cure rate before having access to drugs like ombitasvir / paritaprevir / ritonavir and dasabuvir. Along with individual lives being saved and improved dramatically, early eligibility for and completion of ombitasvir / paritaprevir / ritonavir and dasabuvir is likely to result in financial cost savings to healthcare systems and should be considered. Ultimately, the wisest course is a reasonable balance between cost and clinical best practice in treating as many people as quickly as possible.